

Evaluation of the Indiana Medicaid Preferred Drug List (PDL) Program

Report 3

PERIOD EVALUATED: 10-1-04 to 3-31-05

Presented by:

ACS Government Healthcare Solutions

For State of Indiana Office of Medicaid Policy and Planning And Indiana Medicaid DUR Board

> <u>Primary Author:</u> Michelle Laster-Bradley, Ph.D., M.S., R.Ph. (Project Manager)

> > Contributors:
> > Amy Treon, R.Ph.
> > Jim Adkins, M.S., R.Ph.
> > Cara Lee, PharmD
> > Jilka Patel, PharmD
> > Jennifer Holland

TABLE OF CONTENTS

Executive Summary	4
Introduction	
Objectives	6
Results Summary	
1.) Impact of the Preferred Drug List on Medicaid Medical Costs	
2.) Impact of PDL on Medicaid Recipients' Ability to Obtain Prescription Drugs	
Recipients Followed for 30 Days after a Denied Claim	
3.) Number of Times Prior Authorization was Requested, Approved and Disapp	
4.A) Net Pharmacy Benefit Savings Associated with the PDL Program	
Report Period One: 8/1/02 to 7/31/03 Partitions of Drug Spend	
Report Period Two: 10/1/03 to 9/30/04 (FFY 2004) Partitions of Drug Spend	
Report Period Three: 10/1/04 to 3/31/05 Partitions of Drug Spend	
4.B) Cost to Administer the PDL Program	
Discussion and Conclusions	16
	10
METHODOLOGY	19
CHAPTER 1	
Impact of PDL on Health Outcomes of Indiana Medicaid Recipie	ents by
Measuring Direct Medical Costs	•
Overview and Background	
Methods	
Data	
Inclusion and Exclusion Criteria	
Inclusion Criteria for Therapeutic Classes of Drugs Studied	20
Exclusion Criteria for Therapeutic Classes of Drugs Studied	20
Inclusion Criteria for Recipients	
Cohorts Medical Data Study Period	
Specification of Recipient Outcome Measures.	
Outcome Measure Definitions	
Service Types	
Cost Definition	
Method of Analysis	
Results	
Conclusion	
Discussion and Limitations	30
CHAPTER 2	
The Effects of the Preferred Drug List Program on Medicaid	
Recipients' Access to Medications	22
Introduction	
IIII OUUCUOII	33

Page 2 of 69

12/20/2005

-- continued -- Table of Contents

Report 1 Review	34
Report 2 Review	
Methods	
Results	
Conclusions	
Report 3 Review	
CHAPTER 3	40
Preferred Drug List Program Prior Authorizations	40
CHAPTER 4	
	with the Preferred
Pharmacy Benefit Expenditure Changes Associated	
Pharmacy Benefit Expenditure Changes Associated v Drug List Program	54
Pharmacy Benefit Expenditure Changes Associated v Drug List Program Introduction	54
Pharmacy Benefit Expenditure Changes Associated v Drug List Program Introduction	54
Pharmacy Benefit Expenditure Changes Associated value Drug List Program	
Pharmacy Benefit Expenditure Changes Associated v Drug List Program Introduction	
Pharmacy Benefit Expenditure Changes Associated of Drug List Program	
Pharmacy Benefit Expenditure Changes Associated value Drug List Program	
Pharmacy Benefit Expenditure Changes Associated of Drug List Program	
Pharmacy Benefit Expenditure Changes Associated of Drug List Program	54 54 55 55 56 56 56 56
Pharmacy Benefit Expenditure Changes Associated of Drug List Program	54 55 55 55 56 56 56 56 56
Pharmacy Benefit Expenditure Changes Associated of Drug List Program Introduction Extraction of CMS Rebate Data Preferred Drug List Savings Calculations Factors Affecting PDL Program Savings CMS Rebates Supplemental Rebates Preferred Product Selection Price Changes and Other Cost Factors. Results	54 55 55 56 56 56 56 57

EXECUTIVE SUMMARY

Introduction

The cost of providing prescription drug services for traditional Medicaid fee-for-service (FFS) recipients has risen dramatically. Even so, the Indiana legislature, the Office of Medicaid Policy and Planning (OMPP), and the Indiana Medicaid Drug Utilization Review (DUR) Board have demonstrated an unwavering commitment to address the health care needs for the citizens of Indiana. A major focus for the OMPP and Medicaid DUR Board has been to maximize prescription drug products/services while minimizing the cost to the State of Indiana.

In January 2002, the State of Indiana created a prior authorization (PA) program, the Indiana Rational Drug Program (IRDP), designed to control costs while ensuring appropriate use of prescription drugs for Medicaid recipients. *Indiana Senate Enrolled Act No.* 228 (SEA 228) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid, with prior authorization for drugs not included on the PDL. The PDL program built upon the intent of the IRDP, but encompassed a much wider range of prescription drug classes. As with the IRDP, the purpose of the PDL is to ensure that Indiana Medicaid recipients receive clinically appropriate prescription drugs, while minimizing the cost incurred. The PDL program was introduced in August 2002 for the Primary Care Case Management (PCCM) Program and the Fee-for-Service Program.

The PDL selection process is based upon a non-biased, clinical review of each medication within a given therapeutic class. The Indiana Medicaid Therapeutics Committee (T Committee) composed of physicians and pharmacists, reviews and submits selection recommendations to the Indiana Medicaid Drug Utilization Review (DUR) Board for approval. In finalizing selection of one or more preferred drugs within a therapeutic class, the T Committee and DUR Board give primary consideration to clinical efficacy or therapeutic appropriateness. They then examine cost¹, including consideration of the PDL program's fiscal implications on other components of the State's Medicaid program. Other components include access to care and potential cost shifting. The medications classified as "nonpreferred" may be permitted upon request from the prescribing physician using the published prior authorization process.

12/20/2005

¹ Cost is net of federal rebates.

The first year of the Indiana PDL program consisted of more than 52 therapeutic drug classes implemented over a 13-month period beginning in August 2002². After the first year of phased-in implementations of therapeutic classes, a process of continual improvement to the PDL program began in September 2003, with biannual reviews of PDL classes.

Indiana SEA 228 also provided for evaluation of health outcomes and cost implications of the PDL program. Therefore, an initial evaluation of the health outcomes and cost implications of the Indiana PDL Program after its first year of implementation was conducted by ACS State Healthcare using prescription and medical data from August 2002 to August 2003. The report, containing outcomes evaluation of the PDL program and recommendations for improvement, was submitted to the DUR Board in May 2004.

ACS Government Healthcare Solutions produced a second report as a follow-up evaluation on the health outcomes and cost implications of the Indiana PDL program. The second report, Report 2, evaluated the 2nd year of the PDL program operations using prescription and medical data from October 2003 to September 2004. Report 2 evaluated 54 therapeutic classes either re-reviewed or newly implemented changes by the T Committee and DUR Board in the 2nd year of the PDL program. The follow-up outcomes evaluation and additional recommendations for improvement was submitted to the DUR Board in June 2005.

Both Reports 1 and 2 contained a recommendation to add supplemental rebates as part of the PDL program. States who wish to pursue Medicaid supplemental rebates, in addition to rebates already received under the National Drug Rebate Agreement, have the option to negotiate such rebates with drug manufacturers as specified in Federal law. Rebates received under state supplemental agreements are shared with the Federal government at the same rate as the national or federal rebates. The manufacturers' federal and supplemental rebates are compiled and presented to the T Committee, along with clinical drug information. The T Committee then makes recommendations to the DUR board based upon these economic and clinical factors as to which products should be designated as "preferred". Supplemental rebates were phased-in to the PDL program with some therapeutic classes starting October 26, 2004 and a second group on December 21, 2004.

ACS Government Healthcare Solutions produced this report, Report 3, as an additional follow-up on the health outcomes and cost implications of the Indiana PDL program by evaluating the next six months of prescription and medical data available for analyses. Report 3 evaluated PDL program operations using prescription and medical data from October 1, 2004 to March 31, 2005. This analysis period is approximately from two to 2 ½ years into PDL program operations (the first half of Year 3), or from 26 to 31 months

12/20/2005 Page 5 of 69

² First Data Bank'sTM definition of a "therapeutic class" was used to operationally define the drugs belonging to or grouped within a "therapeutic class" for all PDL evaluation reports. More than 52 therapeutic drug classes were implemented; however, some classes were combined due to lack of claims for analysis at 13-months post implementation. Later, in Years 2 and 3, some classes were reclassified and split into two or more classes by First Data Bank.TM Therefore, 52 classes were evaluated in the first PDL report (12 months post-implementation), 54 classes were evaluated in PDL Report #2 (13-24 months post-implementation), and 62 classes were evaluated in PDL Report #3 (26-31 months post-implementation).

after PDL program operations first began. Report 3 includes analyses of initial savings resulting from the phased-in addition of supplemental rebates to the PDL program in addition to the original legislative requirements listed in the objectives below.

Objectives

The goal of this report is to determine the overall impact of the PDL in accordance with Indiana Code 12-15-35-28(h). The four primary objectives are to evaluate:

- 1.) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.
- 2.) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.
- 3.) The number of times prior authorization was requested, and the number of times prior authorization was: (A) approved and (B) disapproved.
- 4.) The cost of administering the preferred drug list.

Results Summary

1.) Impact of the Preferred Drug List on Medicaid Medical Costs

Of the therapeutic classes evaluated, overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation). It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned to take preferred or nonpreferred drugs; therefore, only association or lack of association can be determined (n=38,724 recipients in Year 1; 23,585 recipients in Year 2; and, 21,127 recipients in the first half of Year 3).

Inclusion/exclusion criteria were applied to all therapeutic classes in the PDL list as shown in Figure E.1.

Figure E.1. Inclusion/Exclusion Criteria for Therapeutic Classes Studied in the Medical Analyses

Therapeutic classes chosen for inclusion in studying medical data were:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, recipients taking medications only in therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report 1. These same recipients in these original 8 therapeutic classes (who were still eligible) were subsequently followed-up in the second and third reports.
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation.
 A relatively large market shift was defined as therapeutic classes with 95% or less preferred market share prior to PDL program implementation.
- Therapeutic classes with approved use as long-term maintenance therapy for chronic illnesses. This
 maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or
 nonpreferred drugs for a long, continuous period of time. Long-term maintenance therapy increases the
 likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated
 influences

Therapeutic classes excluded from medical data analyses were:

- Therapeutic classes with greater than 95% preferred drug market share prior to the PDL implementation.
 These classes were excluded due to an insufficient number of recipients who switched from nonpreferred to preferred in order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it would be impossible to determine if medical expenditures are associated with taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.
- Therapeutic classes with too few recipients taking the medications. The sample size of each therapeutic
 class must be large enough to obtain statistical significance (α = 0.05 with a medium effect size) with
 reasonable power (.80).

After applying the inclusion/exclusion criteria, recipients taking medications from eight therapeutic classes were evaluated in Reports 1 and 2 for differences in total and specific medical expenditures. These eight therapeutic classes were: ACE Inhibitors, Alpha/beta Adrenergic Blocker Antihypertensives, Calcium Channel Blocker Antihypertensives, Loop diuretics, Platelet Aggregation Inhibitors, Thiazolidinediones, Triptans, and Proton Pump Inhibitors.

Recipients receiving medications from one or more of these eight therapeutic drug classes were evaluated over a 6-month pre- and a 6-month post-implementation of the PDL program in Report 1. Report 2 then evaluated those recipients' medical expenditures through the end of Year 2 post-PDL. Report 3 continued to follow medical expenditures of recipients from the original eight classes. Furthermore, three additional classes met the inclusion criteria and were included for evaluation of medical expenses in this report, Report 3. The three new therapeutic classes where recipients' medical expenses were evaluated are: Miotics, Antipsoriatics, and Urinary Antispasmotics/Anti-incontinence drugs.

Of all the therapeutic classes evaluated, the evidence does not demonstrate any statistically significant change in overall medical expenditures six (6), 12 and 31 months after PDL implementation. In other words, recipients affected by the PDL program were not associated with a statistically significant difference in overall medical expenditures when compared to recipients not affected by the PDL program.

Analyses were performed on specific medical expenditures in addition to overall medical expenditures. Specific medical service type expenditures analyzed were: prescriber office visits, inpatient hospital admissions, emergency room services, and laboratory procedures. When examining specific medical service types at six (6), 12 and 31 months after PDL implementation of a therapeutic class, there is no evidence to suggest that specific medical costs (e.g. other health care providers, lab, emergency room services or hospital services) are higher on a wide, systematic scale for recipients taking preferred drugs versus recipients taking non-preferred drugs.

2.) Impact of PDL on Medicaid Recipients' Ability to Obtain Prescription Drugs

Recipients Followed for 30 Days after a Denied Claim

Recipients affected by the PDL program would be those taking a nonpreferred medication before PDL implementation. Affected recipients either switched to a preferred medication, received a prior authorization to continue with their non-preferred medication, or stopped taking their medication due to experiencing a denied claim at the pharmacy. In Report 1, twenty-three classes contained enough claims data 12-months after PDL implementation to assess the PDL program's impact on users' access to medications. Of the 188,508 monthly recipients followed 12-months after the initial PDL program began, only 1,485 (0.78%) experienced a denied claim with no paid claim for a related medication within 30 days. It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies.

For Report 3, the PDL program's impact on users' access to medications after the PDL program had been operating for a long time period was assessed. Retail pharmacy prescription claims were examined at 26 and 31 months after initial implementation. Since nursing home claims were sometimes billed months after the date of service, only outpatient retail pharmacy claims conducted at point-of-sale were analyzed. Of the 203,463 monthly recipients followed for 26-months after, and of the 208,693 monthly recipients followed for 31-months after the initial PDL program began, only 3,288 (1.5%) experienced a denied claim in the two months of October 2004 and March 2005.

A random sample of 1,000 retail pharmacy Medicaid recipients' claims were analyzed during the month of October 2004 after the recipient experienced a denied claim due to a non-PDL prescription claim. Another random sample of 750 were analyzed in the month of March 2005. Of the 1,750 recipients followed from the initial claim rejection due to a non-PDL prescription claim, only 47 recipients (0.023%) in October 2004 and 28 recipients (0.013%) in March 2005 experienced a denied claim with no paid claim for a related medication within the next 30 days.

Overall, the initial number (0.78% without a related claim within 30 days of the denial in the first year) suggest a minimum impact on PDL users. Further, denials diminished monthly as providers gained experience with the program as evidenced by the 0.023% at 26 months and 0.013% at 31 months after the program began.

It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. Claims data does not allow full explanation for the therapy interruptions. For example, there are many potential reasons other than PDL such as: physician sampling of medications, other 3rd party liability, patient compliance, or changes in patient therapy.

To put this into perspective, the rate of nonpreferred claims denials where recipients had no later related claim within the next 30-days is far lower than the 30 to 50% noncompliance rate after receiving medications documented in the literature. Since between 30 to 50% of all patients fail to follow their prescribed therapy once they receive it, noncompliance or lack of persistence with taking medications may be a larger concern. Therefore, analysis in Report #2 examined recipients who were noncompliant (as evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were noncompliant. The results illustrate that the problem with recipients' health outcomes for Indiana recipients are less likely to be related to whether recipients are taking nonpreferred or preferred medications, but rather are more likely to be related to whether recipients will be compliant with taking any medication, whether it is preferred or nonpreferred.

Patterns Revealed

Furthermore, ACS observed some interesting patterns during analysis of denied claims for Non-PDL drugs. The denied claims were primarily for antihypertensive medications, especially Angiotensin Receptor Blockers (ARBs) and ACE Inhibitors. Based upon the patterns observed, it appears that some providers may have been attempting to bypass the intent of the Indiana criteria instituted. For example:

- When eye drop claims denied, a pattern revealed some pharmacy providers resubmitted with an emergency override code and input 3-days as the days supply. This pattern allowed the claim to process and pay; thereby, bypassing the edit criteria.
- When there was a denial for step therapy for ARBs where recipients must have failed an ACE Inhibitor first, a pattern revealed some providers switched the claim from plain ARBs to combination ARBs with HCTZ that had no step therapy criteria. This immediate switch allowed the claim to process and pay; thereby, bypassing the edit criteria.

3.) <u>Number of Times Prior Authorization was Requested, Approved and Disapproved.</u>

During the first six months of federal fiscal year 2005 (10/1/04 to 3/31/05) there were 41,052 PDL program prior authorizations requested. Of the 41,052 PA's requested, 40,432 were approved (98.5%), 513 were disapproved (1.2%) and 107 were suspended (0.3%). The percentage of prior authorizations (PAs) for non-preferred drugs that were disapproved has slightly increased over the two-and-one-half year span from 0.2% PAs disapproved (between August 2002 to December 2002 when the PDL program first began) to 1.2% PAs disapproved in the first half of 2005.

Table E.2 Preferred Drug List Prior Authorization Requests

Time Period	Average # Utilizers per Month	Total All PAs Requested	Approved	% A	# A PUPM	Denied	% D	Sus- pended	% S
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	204,840	80,950	79,200	97.8%	0.0322	193	0.2%	1,557	1.9%
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	208,995	75,705	73,681	97.3%	0.0294	1,177	1.6%	847	1.1%
First 6 months - FFY 2005 Oct 1, 2004 to Mar 31, 2005	205,982	41,052	40,427	98.5%	0.0327	513	1.2%	112	0.3%

4.A) Net Pharmacy Benefit Savings Associated with the PDL Program

Report Period One: 8/1/02 to 7/31/03 Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 8/1/02 to 7/31/03 was an estimated \$642³ million (Chart E.1). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable PDL Classes with Potential to Effect Change (24%) = \$154 m
- AAAX⁴ (considered preferred per statute) (31.1%) = \$200 m
- Classes Not Reviewed⁵ (27%) = \$173 m
- PDL classes with limited⁶ benefit @ >95% preferred prior to implementation (18%) = \$116 m

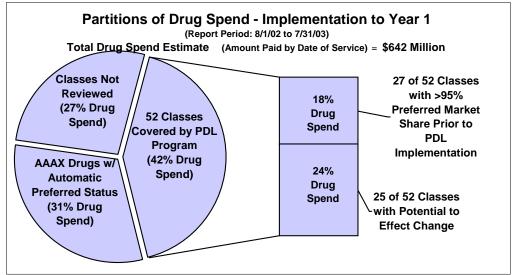


Chart E.1 Partitions of Total Drug Spend (\$642 Million) from 8/1/02 to 7/31/03 Source: ACS State Healthcare Analysis of OMPP data.

Total annualized pharmacy benefit <u>net</u> savings (after CMS [standard Federal] rebate deductions after market share shifts and cost to administer the PDL program) in the **52 PDL classes implemented and evaluated from August 2002 to September 2003** (Year 1 post-PDL implementation) were estimated to be between **\$7.4 to \$8.16 million**.

12/20/2005

³ Estimates are from 8/1/02 to 7/31/03 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program.

⁴ These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

⁵ Drug classes of medications not on the PDL program from August 2002 to August 2003.

⁶ Over 95% of market share were preferred medications prior to implementation

Report Period Two: 10/1/03 to 9/30/04 (FFY 2004) Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/03 to 9/30/04 was an estimated \$736⁷ million (Chart E.2). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable PDL Classes with Potential to Effect Change (14%) \$103 m
- AAAX8 (considered preferred per statute) (35.2%) \$257 m
- Classes Not Reviewed⁹ (24%) \$208 m
- PDL classes with limited¹⁰ benefit @ >95% preferred prior to implementation (26.5%) \$196 m

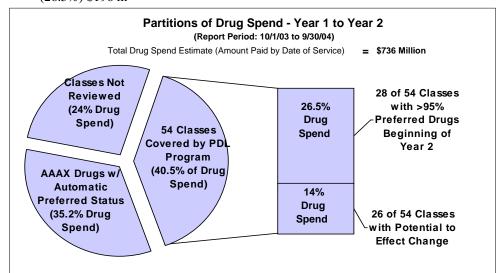


Chart E.2 Partitions of Total Drug Spend (\$736 Million) from 10/1/03 to 9/30/04 Source: ACS State Healthcare Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) due to market share shifts in the 54 PDL classes implemented and evaluated beginning in August 2002 are estimated to be between \$7.40 to \$8.16 million in Year 1, and an additional \$380,000 to (-\$370,000) in Year 2 with two additional classes added to the analysis.

¹⁰ Over 95% of market share were preferred drugs at beginning of Year 2.

12/20/2005

Page 12 of 69

⁷ Estimates are from 10/1/03 to 9/30/04 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program.

⁸ These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

⁹ Drug classes of medications not on the PDL program from October 2003 to September 2004.

Report Period Three: 10/1/04 to 3/31/05 Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/04 to 3/31/05 was an estimated \$392¹¹ million (Chart E.3). This figure includes four major categories partitioned by estimated paid amount:

- AAAX¹² (considered preferred per statute) (30.4%) \$119 M
- PDL Applicable PDL Classes with Potential to Effect Change (14.7%) \$57.4 M
- PDL classes with limited¹³ benefit @ >95% preferred prior to implementation (22.3%) \$87.6 M
- Classes Not Reviewed¹⁴ (32.6%¹⁵) \$128 M

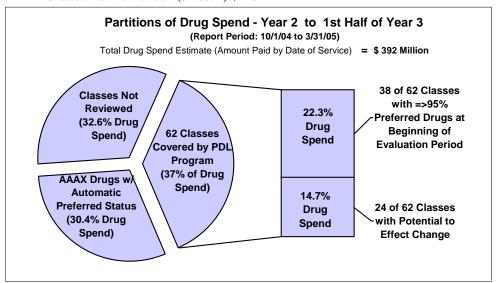


Chart E.3 Partitions of Total Drug Spend (\$392 Million) from 10/1/04 to 3/31/05 Source: ACS State Healthcare Analysis of OMPP data.

Total annualized pharmacy benefit <u>net</u> savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be <u>an additional</u> \$1.11 to \$1.49 million for the first half of Year 3 (October 2004 through March 2005) with 62 PDL classes (8 additional classes added to the analysis).

12/20/2005 Page 13 of 69

¹¹ Estimates are from 10/1/04 to 3/31/05 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program.

¹² These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

¹³ Over 95% of market share were preferred drugs at the beginning of Year 2.

¹⁴ Drug classes of medications not on the PDL program from October 2004 to March 2005.

¹⁵ Expenditures for classes not reviewed grew as a percentage of total spending from Year 2 to the first half of Year 3 because many new drugs with high prices came onto market that had not yet been reviewed.

Total annualized pharmacy benefit <u>net</u> savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) in the 52 PDL classes implemented in August 2002 through July 2003 were estimated to be between \$7.40 to \$8.16 million through Year 1. There was approximately an additional \$380,000 to (-\$370,000) net savings through Year 2 with 54 PDL classes evaluated. Pharmacy benefit <u>net</u> savings (after CMS [standard Federal] and cost to administer the PDL program) in the 62 PDL classes evaluated from October 2004 through March 2005 were estimated to be between an additional \$1.11 to \$1.49 million through the first half of Year 3. This figure does not include additional estimated savings of \$6.81 million from supplemental rebates added to the program beginning in October 2004.

Over the 2½ year PDL program, the overall <u>net</u> pharmacy savings is estimated to be between \$8.15 million to \$10.02 million, plus \$6.81 million in estimated supplemental rebates for a total estimate of \$15–\$16.8 million.

Table E.2 Number of Classes Reviewed, Subsequent Rebate Amounts, and Estimated Savings¹⁶

Time Period	# Classes Affected by the PDL Program	Total Estimated Savings from Market Share Shifts ¹⁷ before Rebates	Total Estimated Rebate Shifts	Total Net Savings ¹⁸ Estimates Minus Federal Rebate Estimates	Estimated Cost of Administering the PDL	Total Net Savings ¹⁹ Estimates Minus Rebates & Estimated Cost of Administering the PDL
Year 1 (8/1/02 to 7/31/03)	52	\$12.4 million	- \$3,524,829	\$8.91 million	-\$750,000 to -\$1.5 million	\$8.16 million to \$7.41 million
Year 2 (10/1/03 to 9/30/04)	54	\$2.06 million	- \$ 931,105	\$1.13 million	-\$750,000 to -\$1.5 million	\$378,929 to -\$370,000
1 st half Year 3 (10/1/04 to 3/31/05)	62	\$1.99 million	- \$ 130,139	\$1.86 million	-\$375,000 to -\$750,000	\$1.49 million to \$1.11 million
Total				\$11.9 million	-\$1.875 million to - \$3.75 million	\$8.15 to \$10.02 million
	ntal Rebate vings	\$6.81 million			GRAND TOTAL	\$15–16.8 Million

¹⁶ All savings and net savings are estimated.

¹⁷ Estimates include both state and federal share.

¹⁸ Estimates include both state and federal share.

¹⁹ Estimates include both state and federal share.

Number of Classes with Little Opportunity for Market Share Shifts and Subsequent Savings

In 27 of 52 PDL classes studied in Year 1²⁰, in 28 of 54 PDL classes studied in Year 2, and in 38 of 62 PDL classes studied in the 1st half of Year 3, preferred drugs selected by the Indiana Medicaid Therapeutics Committee and accepted by the DUR Board did not provide opportunity for either any or very limited market share change because either <u>all</u> drugs or \geq 95% of drugs within the class were selected as preferred, or because <u>utilization</u> in the class was already greater than 95% preferred, but less than 100% preferred.

Table E.3 Number of Classes Reviewed and Percent Preferred - Year 1

# Classes	Year 1 Results	% Before Implementation	% Preferred End of Year 1
52	TOTAL ALL PDL PROGRAMS	75.2%	95.8%
	Totals for Classes With Only Limited Potential For		
27	Market Share Changes (≥95% & including 100%)		
	Totals for Classes with Substantial Potential For		
25	Change (0% to < 95%)		

Table E.4 Number of Classes Reviewed and Percent Preferred - Year 2

# Classes	Year 2 Results	% Preferred at End of Year 2
54	TOTAL ALL PDL PROGRAMS at end of YEAR 2	93.8%
	Totals for Classes With Only Limited Potential For Market	
28	Share Changes (≥95% & including 100%)	
	Totals for Classes with Substantial Potential For Change	
26	(0% to< 95%)	

Table E.5 Number of Classes Reviewed and Percent Preferred - 1st Half of Year 3

# Classes		% Preferred at End of 1 st Half of Year 3
62	TOTAL ALL PDL PROGRAMS at end of 1st Half of YEAR 3	98.7%
	Totals for Classes With Only Limited Potential For Market	
38	Share Changes (≥95% & including 100%))	
	Totals for Classes with Substantial Potential For Change	
24	(0% to< 95%)	

Preferred Drug Market Share Percentage Shifts

12/20/2005

Overall, the **preferred drug market share** shifted from approximately **75.2% to 95.8%** during the Year 1 period, then shifted slightly back toward nonpreferred drugs to approximately **93.8%** preferred at the end of Year 2. For the 1st half of Year 3, the preferred drug market share was **98.7%**.

Page 15 of 69

²⁰ Two classes in Year 1 were newly implemented and did not yet have enough data for analysis.

Sometimes more expensive PDL drugs were chosen for clinical reasons, based on anticipation of better outcomes. Additionally, some increase in expenditures occurred due to unanticipated rebate or product price changes occurring after the selection of preferred drugs. Expenditures for medications considered preferred per statute – antianxiety, antidepressant, antipsychotic and cross-indicated drugs – have increased, but the percentage of total drug expenditures from Year 1 to Year 2 to 1st half of Year 3 has remained constant (31% to 30.4% to 30.4% respectively).

4.B) Cost to Administer the PDL Program

As referenced in Report 2, ACS and OMPP have jointly estimated this cost to be between \$750,000 and \$1.5 million annually.

Discussion and Conclusions

In response to increases in prescription drug spending and utilization, many public-sector pharmacy benefit programs have been developing and implementing a variety of innovative policy solutions for more effective management of pharmacy benefits. One of the methods that several state Medicaid agencies have implemented is the preferred drug list (PDL) program. The concept behind the PDL program is to improve the quality of pharmaceutical care by ensuring that the most clinically appropriate drug is used, while taking into account the relative costs of the available therapeutically equivalent alternatives. PDL programs may be able to address the problems associated with:

- Recipients who rarely see or pay the true costs of their drugs; and therefore have no
 incentive to choose less expensive, yet equally effective medications.
- Prescribers who lack current knowledge of the true costs of medications being prescribed.

This evaluation demonstrates that a Preferred Drug List program does decrease net drug expenses; however, the most substantial net savings are realized within the first year of the PDL program when the largest number of recipients shift from nonpreferred drugs to preferred drugs. Furthermore, the market share movement identified through this evaluation suggests that educating prescribers to prescribe and recipients to utilize preferred drugs works. As a result of moving market share to the preferred products, the PDL program produced savings.

Additionally, after following nearly 38,000 recipients in eight therapeutic classes for 2 ½-years post-PDL implementation, no evidence was uncovered to suggest an association between the PDL and negative impacts on the quality of care or the ability for recipients to obtain medications. Specifically, there is no evidence at 6-months, 2-years, or 2 ½ years (31 months) post-PDL implementation to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospital services is occurring on a wide, systematic scale.

12/20/2005 Page 16 of 69

Although there were documented savings, these savings may have been lessened by three key factors.

- Standard federal rebates Savings resulting from the PDL policy were reduced after considering the impact of lost CMS federal rebates from some preferred drugs. Higher-priced nonpreferred drugs sometimes had proportionately higher corresponding CMS rebates. When the drugs with higher rebates lose market share under a PDL program, rebate amounts can be reduced.
- Lack of readily available, timely data for decision support Data on relative cost-effectiveness and net cost of drug products, after applying rebates, were not readily available at the beginning of the program. In the past, because each manufacturer applies its rebate after-the-fact, only estimates of the true net cost for drugs can be made until several months after sales are completed. ACS has recently employed modeling tools that now allow for better projections of the cost implications of shifting market share among medications in a PDL therapeutic class.

• Limits to savings potential:

- o Some PDL classes had a high percentage of pre-implementation usage of the preferred medications offering little opportunity for savings.
- Some preferred drugs' net costs were higher than the nonpreferred drugs (chosen on clinical advantage).
- o Some preferred drugs underwent unexpected price increases.

Several solutions have potential to address the reduction of savings from the factors listed above. Savings can best be achieved if a PDL program is combined with methods to increase purchasing power. For example:

- Limit the number of preferred drugs within a given therapeutic class The amount of savings is directly related to the ability to increase the market share of the more favorably priced medication within a therapeutic class. Moreover, the more preferred products, the less opportunity to move market share and therefore less potential for savings. Assuming that medications are clinically equivalent, the smaller the list of preferred drugs, the more potential to move market share and obtain supplemental rebates (discussed below).
- Add and continue with supplemental rebates —Supplemental rebates for Medicaid pharmacy claims are a form of state action that increases competition in drug pricing. Increased competition helps drive pricing down in a free market where manufacturers are allowed to set prices in accordance to available competition. In a therapeutic class where numerous brand drugs are found to be clinically equal, supplemental rebates encourage competition by allowing manufacturers to submit progressively higher rebate bids. The manufacturer benefits from obtaining greater market share while the State benefits financially in the form of supplemental rebates. Supplemental rebates cannot be obtained

12/20/2005 Page 17 of 69

separately from the PDL program. Both the PDL and supplemental rebate programs are needed because without a PDL, there would be no basis for negotiating or the State receiving supplemental rebates on drugs chosen as preferred.

Savings have already shown to be further enhanced when supplemental rebates are obtained as part of the PDL program and are calculated into the PDL savings evaluation. Currently, a supplemental rebates program has been phased-in. An early savings analysis reveals that for the first 6-months of supplemental rebates, additional savings are estimated to be \$ 6.81 million. This is in addition to savings obtained through the regular PDL program.

- Remove "AAAX" drugs from Automatic Preferred Status The General
 Assembly could consider removing automatic preferred status of anti-anxiety
 drugs, antidepressants, antipsychotics, and cross-indicated drugs that constitute
 approximately 30% of the prescription drug budget at the time of this study. The
 AAAX drugs are quickly gaining an increasing percentage of the prescription
 drug budget.
- Broaden scope of class reviews to encompass "Classes Not Reviewed"
- Consider fail first PA processes and consider modifying fail first procedures
 to limit health care providers who are taking advantage of loopholes; Fail
 Preferred agent prior to Non-Preferred Override Modify the PA processes
 to require failure of the preferred drug prior to granting PA approval for the nonpreferred drug.

In sum, by limiting the number of preferred drugs within a therapeutic class where clinical outcomes are equivalent, choosing less costly preferred drugs, adding supplemental rebates, removing all or some of the "AAAX" drugs from automatic preferred status, and/or broadening the scope of the drug class reviews to encompass the classes not reviewed, the potential for overall savings increases.

METHODOLOGY

CHAPTER 1 IMPACT OF PDL ON HEALTH OUTCOMES OF INDIANA MEDICAID RECIPIENTS BY MEASURING DIRECT MEDICAL COSTS

Overview and Background

Indiana Senate Enrolled Act No. 228 (SEA 228) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid with prior authorization for drugs not included on the PDL. The concept behind the preferred drug list program is to ensure that Indiana Medicaid recipients receive the most effective prescription drugs available at the best possible price.

Common opposition to PDL programs has been based upon unsubstantiated allegations that negative health consequences may occur due to changes in medication therapy. The Indiana legislature required the Indiana Office of Medicaid Policy and Planning (OMPP) to determine if the PDL program served its intent of promoting efficacious and safe drug therapy while minimizing the expenditure to the State.

OMPP requires ACS State Healthcare to conduct a study to analyze the Indiana preferred drug list program (PDL) to determine if the PDL results in a negative impact on the health outcomes of Medicaid recipients as well as any cost shifting to other health care providers, laboratory, emergency or hospital services.

This study uses retrospective, paid claims data to evaluate recipient outcomes that may be related to implementation of the PDL program. Any changes in medical utilization or costs for those affected by the PDL program, relative to those not affected, would be *indicators of a possible association* between the PDL program and health outcomes.

Methods

Data

The data for this study were derived from the historical paid claims files from the Indiana Medicaid program. Medical data extracts were created and stored on ACS State Healthcare data warehouse for the period of March 1, 2002 to March 31, 2005.

Inclusion and Exclusion Criteria

Inclusion Criteria for Therapeutic Classes of Drugs Studied

Therapeutic classes were <u>included</u> in medical analyses for the first study under the following conditions:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, at the time medical data were extracted for the first study in January 2004, recipients taking medications only in therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report 1. These same recipients in these original 8 therapeutic classes (who were still eligible) were subsequently followed-up in the second and third reports.
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation. This criterion was defined as drugs with 95% or less preferred drug use prior to PDL program implementation.
- Therapeutic classes approved for use as long-term maintenance therapy for chronic illnesses. This maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or nonpreferred drugs for a long, continuous period of time. Long-term maintenance therapy increases the likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

Exclusion Criteria for Therapeutic Classes of Drugs Studied

Therapeutic classes are excluded from analyses under the following conditions:

- Therapeutic classes in which greater than 95% of recipients used a preferred drug
 prior to the PDL implementation. These classes were excluded due to an
 insufficient number of recipients who switched from nonpreferred to preferred in
 order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal
 fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined
 from prescription claims if a recipient terminated therapy due to decreased
 symptoms or because the PDL program limited access to the medication. Hence, it
 would be impossible to determine if medical expenditures are associated with

12/20/2005 Page 20 of 69

taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.

• Therapeutic classes with too few recipients taking the medications. The sample size of each therapeutic class must be large enough to obtain statistical significance ($\alpha = 0.05$ with a medium effect size) with reasonable power (.80).

After applying the criteria to the therapeutic classes for the PDL, this study covered recipients receiving medications in the following eight original therapeutic classes for Reports 1 and 2:

- ACE Inhibitors implemented in September 2002
- Proton Pump Inhibitors implemented in September 2002
- Alpha/Beta Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with Calcium Channel Blockers & Loop Diuretics for analyses)
- Calcium Channel Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with October 2002 Alpha/Beta Blocker for analyses)
- Loop Diuretics implemented in October 2002 (Grouped with October 2002 Antihypertensives above for data analyses)
- Platelet Aggregation Inhibitors implemented in October 2002
- Thiazolidinediones implemented in December 2002
- Triptans implemented in December 2002

For Report #2, recipients were selected from the newer therapeutic classes implemented in the 2nd year of the PDL program. Sample sizes were evaluated. (See Table 1.1). Table 1.1 details the samples sizes of the new therapeutic classes of chronic medication that had the potential to meet medical study inclusion criteria.

The conclusion was made that there was not a large enough sample size to follow the medical or prescription data, and that the new recipients would not add anything meaningful if analyzed. Therefore, Report #2 followed-up recipients in the original eight therapeutic classes for a longer medical study period in year 2 of the PDL program.

For Report #3, recipients receiving medications in the original eight therapeutic classes were followed for the 6-month post-period of 26- to 31-months or 2 ½ years post PDL implementation. Additionally, the following therapeutic classes met the inclusion criteria and recipients taking medications in these new classes were evaluated for medical expenditures:

- Antipsoriatics implemented in July 2003
- Miotics and Intraocular Pressure Reducers implemented in July 2003
- Urinary Antispasmotics/ Antiincontinence Agents implemented in May 2003

Table 1.1. Recipient Summary Data from PDL Changes in Year 2 of the PDL Program

INDIANA MEDICAID

Participant Counts Involved with Year 2 PDL Changes Only in 6 Major Therapeutic Classes

Criteria:

- 1. If > 65% days supply + minimum days =>59, then labeled as "Preferred" or "Non-Preferred"
- 2. If < 59 days supply, then labeled as "Insufficient quantity" to determine PDL status
- 3. If < 65% days supply + minimum days =>59, then labeled as "Mixed PDL/Non-PDL Users"

ACE Inhibitors

ACE Inhibitors with CCB

Participant ID Count	PRE-PDL Period	Post Period
49	Insufficient Quan	Insufficient Quan
69	Insufficient Quan	PDL
1	Mixed	Insufficient Quan
2	Mixed	PDL
1	NPDL	Insufficient Quan
5	NPDL	PDL
4	PDL	Insufficient Quan
1	PDL	Mixed
2	PDL	NPDL
34	PDL	PDL

Participant ID		
Count	PRE-PDL Period	Post Period
64	Insufficient Quan	Insufficient Quan
2	Insufficient Quan	Mixed
63	Insufficient Quan	NPDL
1	Mixed	NPDL
3	NPDL	Insufficient Quan
14	NPDL	NPDL
1	PDL	Mixed
4	PDL	NPDL
3	PDL	PDL
155		

168

HMG CoA Reductase Inhibitors

K+ Sparing Diuretics

Participant ID		
Count	PRE-PDL Period	Post Period
31	Insufficient Quan	Insufficient Quan
1	Insufficient Quan	Mixed
30	Insufficient Quan	NPDL
4	NPDL	NPDL
4	PDL	Insufficient Quan
2	PDL	Mixed
4	PDL	NPDL
70		

Participant ID		
Count	PRE-PDL Period	Post Period
9	Insufficient Quan	Insufficient Quan
2	Insufficient Quan	Mixed
6	Insufficient Quan	NPDL
3	Insufficient Quan	PDL
20		

76

B-Blockers

Participant ID	PRE	Post
4	Insufficient Quan	Insufficient Quan
1	Insufficient Quan	Mixed
3	Insufficient Quan	NPDL
2	NPDL	NPDL
2	PDL	NPDL

12

Inclusion Criteria for Recipients

Recipients were selected for analysis, if they:

- Had a minimum of 6-months of pre- and 6-months of post- prescription and medical claims history available for Study 1, and two years post- prescription and medical data for follow-up Study # 2, and 31 months post- prescription and medical data for follow-up Study # 3.
- Were taking drugs in one of the above therapeutic classes and had at least two PDL-related claims in the three-month period prior to PDL implementation. Recipients of PDL medications were further categorized as Preferred Recipients if at least 80 percent of their PDL-related claims were for preferred drugs; they were Nonpreferred Recipients if at least 80 percent of their PDL-related claims were for nonpreferred drugs. If their usage was mixed not predominantly preferred or nonpreferred recipients were excluded from study.

Cohorts

Recipients were categorized by what happened in the three-month period following PDL implementation. There were recipients who: (1) Changed from nonpreferred drugs to preferred, (2) Changed from preferred drugs to nonpreferred, (3) Did not change from a preferred agent, (4) Did not change from a nonpreferred agent, (5) Terminated nonpreferred therapy, and (6) Terminated preferred therapy.

The cohorts of particular interest were:

- a. Cohort 1 (Changed Therapy, Persisted on Therapy Group): Recipients taking a nonpreferred medication for 6-months before implementation of the PDL list and switched to a preferred medication after PDL program implementation, and persisted with the PDL therapy for up to 2 ½ years through September 2004 to March 2005.
- b. Cohort 2 (No Change Group, Persisted on Preferred Therapy): Recipients already taking preferred drugs 6-months both before and after PDL program implementation, and persisted with the preferred therapy for up to 2 ½ years through September 2004 to March 2005.

Recipients with gaps between paid claims in excess of 60 days were excluded from the multivariate analysis of variance (MANOVA) due to the possibility of noncompliance. By definition, recipients with 60-day gaps in paid prescription claims did not utilize Medicaid services for prescriptions and were classified as not having continuous therapy with a drug in one of the therapeutic classes studied. Although patients who may have been non-compliant with their therapy are important, the purpose of this study was to measure the effects of the drugs in the PDL program. So, care was given to our recipient study group to not bias the study with the effects of non-compliance mixed within.

12/20/2005 Page 23 of 69
ACS Government Healthcare Solutions

Medical Data Study Period

Analyses of the effects of PDL implementation on medical utilization and costs was limited to certain therapeutic groups where potential changes were most likely to have occurred as a result of PDL implementation. Study period one was 6-months prior to and 6-months after each specific therapeutic class' PDL implementation. The month of implementation was excluded in the medical analyses since most implementations occurred mid-month. Study period two was 12-months post- to two years post-implementation. Study period three was 26 to 31 months post-implementation (10/1/04 to 3/31/05).

Specification of Recipient Outcome Measures

Selected outcomes measures studied are expenditures for physician office visits, emergency room services, laboratory services, and inpatient hospital admissions. Medical outcomes were evaluated 6-months before and either 6-month period, 12-months or 31 months after implementation month for each of the two groups of recipients per therapeutic class studied. The month of PDL implementation for the associated therapeutic class was assigned a null period in which no measurements were taken.

Outcome Measure Definitions

Only services related to the disease states treated with the therapeutic class being studied were used in calculating medical expenditures for each service type. This allows a more detailed, narrow scope of expenditures; ensuring that only the expenditures associated with changes in therapy are being included. For example, physician office, lab, or hospital expenditures associated with motor vehicle accidents or broken bones are unrelated to changes in antihypertensive therapy and therefore were not included in measuring expenditure changes between groups. Specific sample sizes, p-values, and observed power for each therapeutic class are reported with each therapeutic class and type of expenditure analyzed.

Inpatient hospital services were measured as a count of each admission date per recipient ID and all expenditures associated with each unique recipient ID per admission date on the inpatient UB-92 claims. Inpatient hospital expenditures were measured only for services related to the disease state associated with the therapeutic class being studied. For example, when analyzing ACE Inhibitors and Antihypertensives, only the DRG codes for cardiovascular services were measured (see Table 1.2). For thiazolidinediones, expenditures associated with the specific DRG codes for cardiovascular, endocrine, and kidneys were used.

Table 1.2 Procedure Codes & DRG Codes Used to Define Specific Types of Medical Services Studied

Service Types	Detail Procedure Codes	DRG Codes
	99201-99215	
Physician Office or Outpatient Visits	99241-99245	N/A
	99354-99357	
	99361-99380	
Laboratory Services	80000 – 89999	N/A
	95250 – glucose monitoring	
Emergency Physician Services	99281-99288	N/A
Services Related to:		N/A
End-Stage Renal Disease & Dialysis	90918- 90999	302-333
	92950 – 93981 (includes	103-145;
Cardiovascular	extremity arterial & venous	478,479,514-518;
	studies)	525-527
Endocrine		285-301
Pulmonary	94010 - 94799	N/A
Gastroenterology	91000-91299	N/A
Ophthalmology	92002 - 92499	N/A
Allergy & Clinical Immunology	95004 – 95199	N/A

Physician office visits were defined by detail procedure codes associated with outpatient or office services involving physician evaluation and management of patients (shown in Table 1.2). Laboratory services are defined by detail procedure codes in the range: 80000-89999 and 95250 (glucose monitoring). Emergency services are defined by locating the emergency physician services by procedure codes 99281-99288, and then rolling up the costs of all detail numbers associated with those emergency services claims.

Cost Definition

To explore the impact of drug use patterns associated with the PDL program on medical costs, Indiana Medicaid claims were partitioned by type of service. The amount actually paid directly by the Indiana Medicaid program minus recipient co-pays and other insurance was used as the Amount Paid for expenditures. We acknowledge that this definition does not capture the full costs of medical expenditures since Medicare is the primary payer for Medicare-covered services and Indiana Medicaid would pay only the balance. However, this study is only measuring differences in paid amounts between two groups. Since we are only interested in payment changes between groups, we contend that amount paid is sufficient because it applies equally to both groups.

Method of Analysis

Comparison of mean medical expenditures was conducted for each therapeutic class by using MANOVA or a multiple comparisons analysis of variance (ANOVA).

12/20/2005 Page 25 of 69

ACS Government Healthcare Solutions © 2005 All rights reserved. Information was deemed proprietary and confidential.

The issue explored was whether recipients affected by the PDL (i.e., those whose medications were changed from nonpreferred to preferred drugs) showed significant mean differences in expenditures compared to those not affected by the PDL (i.e. those who had no change in their medication). If any changes were observed, post hoc multiple comparisons were conducted to determine which group had greater expenditures. Comparing mean expenditures between groups is one way to estimate if there were any detrimental effects to the health of recipients associated with the PDL program. If detrimental effects occurred from the PDL program drug therapy, patients might require greater medical expenditures from increased physician visits, hospitalizations, and lab monitoring procedures.

Results

For recipients taking medications in any of the eight therapeutic classes as a covariate, no statistically significant differences were observed in the overall medical expenditures (p=0.001, power=.40) or in specific medical service types (p=0.006 MD Paid, 0.072 power; p=0.003 ER Paid, 0.225 power; p=0.002 Lab, 0.377 power; p=0.001 total Medical expenditures, p=0.402 power) between the two groups (recipients affected by the PDL program versus recipients not affected). Table 1.3 illustrates the between-subjects effects.

Physician office visit expenditures were the only medical data where a problem was seen. There were many zeroes in the paid amounts that skewed the data causing the Levene's test of equality of error variances to be statistically significantly different. However, a natural log transformation did not help rectify the situation. In looking at the differences between means in physician office visit paid data, there does not appear to be large differences between means. Therefore, this test seems to be robust enough to capture the correct outcomes.

Table 1.3 General Linear Model –ANOVA (Tests of Between Subjects Effects & Descriptive Statistics)

Tests of Between-Subjects Effects

		Type III Sum of					Partial Eta	Noncent.	Observed
Source	Dependent Vari		df	Mean Square	F	Sig.		Parameter	
Corrected Mo	MDPaid	34420941.322b	2	17210470.661	38.863	.000	.006	77.726	1.000
	ERPaid	1913238.216°	2	956619.108	20.791	.000	.003	41.582	1.000
	LabPaid	1445112.157 ^d	2	722556.078	12.843	.000	.002	25.686	.997
	MDEncounterPa	989029847.282 ^e	2	194514923.641	7.562	.001	.001	15.123	.946
	TotalMedPaid	184569964.684 ^f	2	92284982.342	10.369	.000	.002	20.738	.988
Intercept	MDPaid	603530893.418	1	603530893.418	362.836	.000	.092	1362.836	1.000
	ERPaid	28678166.001	1	28678166.001	623.291	.000	.044	623.291	1.000
	LabPaid	53799346.554	1	53799346.554	956.255	.000	.066	956.255	1.000
	MDEncounterPa	599028076.651	1	599028076.651	574.766	.000	.041	574.766	1.000
	TotalMedPaid	892584766.026	1	892584766.026	663.542	.000	.047	663.542	1.000
TheraClass6	MDPaid	32260240.354	1	32260240.354	72.847	.000	.005	72.847	1.000
	ERPaid	1887927.811	1	1887927.811	41.032	.000	.003	41.032	1.000
	LabPaid	1443991.906	1	1443991.906	25.666	.000	.002	25.666	.999
	MDEncounterPa	987799079.692	1	987799079.692	15.117	.000	.001	15.117	.973
	TotalMedPaid	156091624.662	1	156091624.662	20.597	.000	.002	20.597	.995
Persistence	MDPaid	84543.595	1	84543.595	.191	.662	.000	.191	.072
	ERPaid	66513.086	1	66513.086	1.446	.229	.000	1.446	.225
	LabPaid	152335.971	1	152335.971	2.708	.100	.000	2.708	.377
	MDEncounterPa	301357423.954	1	301357423.954	1.525	.217	.000	1.525	.235
	TotalMedPaid	591414928.057	1	591414928.057	2.931	.087	.000	2.931	.402
Error	MDPaid	977136973.448	3497	442849.298					
	ERPaid	621009092.276	3497	46010.898					
	LabPaid	759347578.602	3497	56260.471					
	MDEncounterPa	602308778.636	3497	197644091.930					
	TotalMedPaid	488666751.585	3497	201784742.295					
Total	MDPaid	881688044.921	3500						
	ERPaid	763089887.285	3500						
	LabPaid	989758266.125	3500						
	MDEncounterPa	056655531.129	3500						
	TotalMedPaid	301442363.652	3500						
Corrected To	MDPaid	011557914.770	3499						
	ERPaid	622922330.492	3499						
	LabPaid	760792690.759	3499						
	MDEncounterPa	591338625.918	3499						
	TotalMedPaid	673236716.269	3499						

a.Computed using alpha = .05

b.R Squared = .006 (Adjusted R Squared = .006)

c-R Squared = .003 (Adjusted R Squared = .003)

d.R Squared = .002 (Adjusted R Squared = .002)

e.R Squared = .001 (Adjusted R Squared = .001)

f-R Squared = .002 (Adjusted R Squared = .001)

Estimates

				95% Confidence Interval		
Dependent Variable	Persistence	Mean	Std. Error	Lower Bound	Upper Bound	
MDPaid	No Change: PDL before, PDL Persistently to Yr 2	459.066 ^a	7.363	444.633	473.499	
	NonPDL before, Change to PDL, Persistent with PDL Therapy	464.488 ^a	9.661	445.550	483.425	
ERPaid	No Change: PDL before, PDL Persistently to Yr 2	100.102 ^a	2.373	95.450	104.755	
	NonPDL before, Change to PDL, Persistent with PDL Therapy	104.911 ^a	3.114	98.807	111.015	
LabPaid	No Change: PDL before, PDL Persistently to Yr 2	127.518 ^a	2.625	122.373	132.662	
	NonPDL before, Change to PDL, Persistent with PDL Therapy	134.795 ^a	3.444	128.046	141.545	
MDEncounterPaid	No Change: PDL before, PDL Persistently to Yr 2	5857.420 ^a	155.558	5552.503	6162.336	
	NonPDL before, Change to PDL, Persistent with PDL Therapy	6181.102 ^a	204.100	5781.038	6581.166	
TotalMedPaid	No Change: PDL before, PDL Persistently to Yr 2	6377.740 ^a	157.179	6069.646	6685.833	
	NonPDL before, Change to PDL, Persistent with PDL Therapy	6831.185 ^a	206.227	6426.952	7235.418	

a. Covariates appearing in the model are evaluated at the following values: TheraClass6 = 2.96.

Levene's Test of Equality of Error Variances

	F	df1	df2	Sig.
MDPaid	8.575	1	13498	.003
ERPaid	.284	1	13498	.594
LabPaid	.094	1	13498	.759
MDEncounterPaid	.007	1	13498	.935
TotalMedPaid	.318	1	13498	.573

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept+TheraClass6+Persistence

Descriptive Statistics

	Persistence	Mean	Std. Deviation	N
MDPaid	No Change: PDL before, PDL Persistently to Yr 2	\$470.8451	\$679.48317	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	\$444.6843	\$646.12635	5035
	Total	\$461.0881	\$667.33318	13500
ERPaid	No Change: PDL before, PDL Persistently to Yr 2	\$102.9519	\$210.53434	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	\$100.1205	\$221.83754	5035
	Total	\$101.8959	\$214.81577	13500
LabPaid	No Change: PDL before, PDL Persistently to Yr 2	\$130.0100	\$240.55129	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	\$130.6057	\$232.03119	5035
	Total	\$130.2322	\$237.40090	13500
MDEncounterPaid	No Change: PDL before, PDL Persistently to Yr 2	\$5,970.7773	\$14,283.86305	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	\$5,990.5216	\$13,691.72791	5035
	Total	\$5,978.1412	\$14,065.42695	13500
TotalMedPaid	No Change: PDL before, PDL Persistently to Yr 2	\$6,511.4356	\$14,283.85947	8465
	NonPDL before, Change to PDL, Persistent with PDL Therapy	\$6,606.4110	\$14,099.55478	5035
	Total	\$6,546.8579	\$14,214.95118	13500

Conclusion

The Indiana DUR Board and OMPP have demonstrated a commitment to addressing the health care needs of its Medicaid population. OMPP is committed to providing quality health care, while maximizing the financial resources available. The PDL program was implemented to ensure the quality of care and minimize the expenditures to the State of Indiana, while minimizing the impact to recipients and health care providers. As a consequence, OMPP is required to analyze the impact of the PDL program and identify any unintended consequences associated with the PDL program.

In the eight therapeutic drug classes and 38,724 recipients evaluated over both a 6-month pre- and post-implementation of the PDL program, the evidence does not suggest that recipients affected by the PDL (by requiring a change to a preferred medication) have higher medical costs as a result. Following up on the same recipients at one and two-years post-implementation, 23,585 were still eligible for study. In the 23,585 recipients evaluated one-year and two-years post-implementation, the evidence does not support higher cost shifting to other specific medical expenditures, such as increased lab tests. The same pattern was found for the 13,498 recipients with medical expenses out of the 21,127 recipients studied in the first half of year 3 who were still taking medications and who were still eligible.

In conclusion, recipients impacted by the PDL program do not demonstrate a statistically significant increase in medical expenditures when compared to recipients not affected by the PDL program.

Discussion and Limitations

Caution must be used in the interpretation of these results. The following limitations should be noted when evaluating the findings of this section.

Retrospective studies, such as this one, are subject to numerous biases. Since it is impractical to operate a Medicaid program like a controlled clinical trial, there may be differences observed in user groups that are not necessarily attributable to the program itself but to other confounding factors that are difficult to control for or are unknown. For this reason, results of retrospective observational studies such as this one are considered associations and not causal.

Furthermore, the type of statistical tests performed can help account for biases known to be a part of the analyses. The between-group variances were significantly different; meaning, one of the assumptions of ANOVA were violated. Yet, ANOVA is known for being a very robust test. A repeated measures analysis was conducted due to its design advantage in reducing the unsystematic variability in the design and so provides greater power to detect effects. Further analyses using the Bonferroni method were performed to verify results. The Bonferroni method has been shown to be extremely robust; it controlled alpha levels and Type 1 error rates the best out of all the univariate techniques.

12/20/2005 Page 30 of 69

In the first study by using medical data that was only 6-months post implementation, Levene's test of equality of error variances was significant for many therapeutic classes and medical service type expenditures, meaning the between-group variances are significantly different. Levene's test of equality of error variances was most often significant for emergency room services, laboratory, and inpatient hospital services where number of incidences and sample size are low. When sample sizes are low, some recipients in this study may have measurements much different from the average user (outliers) and thus can "skew" the results. The large amount of zero paid amounts for physician office expenditures skewed the data such that even a natural log transformation did not correct the problem. However, the tests used to analyze the data in this study are "robust" as to limit the effect of "skewed" data.

In the follow-up second study, Levene's test was significant only for physician office expenditures. This phenomenon can be explained by the lag time of receiving medical claims data. Having only 6-months post-implementation data for the first study was a significant problem. After two years, gaps in the medical data for 6-month to 1-year post implementation had subsided and increased the validity of the medical data. Since prescription claims data are point-of-sale, there is virtually no lag time on prescriptions claims data. However, medical claims data submission is still paper driven in some offices, and is much slower in getting into the database.

It was mentioned in the first Report that steps should be taken in future studies to equalize the variances through data transformation such as taking the square root of, rate of change of all values of the dependent variable, or removing outliers prior to analyses. Data transformation was recommended for future follow-up studies in Report 1.

There is an apparent selection bias inherent in the two cohorts studied. This means that there are systematic differences in the groups studied based on the way the recipients were selected into the study groups. For example, in some therapeutic classes (or disease states), recipients who were already taking the preferred drugs were stabilized and were inherently using less medical resources both pre- and post-PDL implementation than those in the nonpreferred groups. It would make sense that users of a medication that a therapeutics committee deemed to be clinically superior would have different health outcomes than those who used a "nonpreferred" potentially inferior medication, then switched to the "preferred" medication. Conversely, in some therapeutic classes where the medications were equally effective, recipients switched from a newer, more expensive "nonpreferred" medication may not be as sick as a recipient who has been taking an older, less expensive "preferred" medication for a long time. Thus, the results observed from each therapeutic class studied may not apply to other therapeutic classes.

The medical analyses in this study are based on the paid amounts by the State of Indiana Medicaid Program. Paid amounts (expenditures that the state incurred) are only one measure of costs of providing services. Fluctuations in third party liability (TPL) expenditures and co-pays are not accounted for when using paid amounts. There is also the possibility of missing services performed that have not yet been filed or paid. For

these reasons, this study does not capture trends in the total overall expenditures for medical services but rather the State's liability for the services studied.

The 6-month post-PDL study period was a relatively short-term follow-up. Medical illnesses may take longer than 6 months to develop and further follow-up with longer post-periods should be conducted. The two largest limitations to the first study, low power measures in many of the drug classes studied and the highly skewed medical data were rectified with the second iteration of this study, except for specific physician office visits. Any effects of the program became more evident during this subsequent PDL evaluation and we were able to have much more confidence in the statistical results.

CHAPTER 2

THE EFFECTS OF THE PREFERRED DRUG LIST PROGRAM ON MEDICAID RECIPIENTS' ACCESS TO MEDICATIONS

Introduction

Under a PDL program, claims for nonpreferred medications cause a denial edit to post on the dispensing pharmacy's point of service response. This edit directs the pharmacist to contact the prescriber. The prescriber may either instruct the dispensing pharmacist to dispense a "preferred medication," call an ACS consulting pharmacist to discuss alternative therapy, or request prior approval from the Indiana Medicaid program or its contractor to use the originally prescribed "nonpreferred" medication.

Claim denials may also occur if there is an attempt to refill a prescription too early. The prescriber may discuss any of these events with the reviewing pharmacist to arrive at an appropriate course of action. The possible outcomes of denied claim events are: 1) the new prescription is filled without delay, 2) the new prescription is filled after a delay, or 3) no related or follow-up prescription is prescribed.

Concern has been expressed by some patient advocates, manufacturers, prescribers, patients and others that a Preferred Drug List program may cause some patients harm by either causing a delay in starting on prescribed medications or by potentially "restricting access" to medications. Specifically, if pharmacists cannot contact the prescriber and bring resolution to the denied claims rather quickly, patients may leave the pharmacy with no medication. Some patients will eventually receive medications after a delay; while, other patients may choose not to follow-up later thereby, in essence, terminating therapy previously begun, or never starting the drug therapy.

First, not all delays or therapy terminations associated with a PDL program are undesirable. Delays can occur between the time of the denial and the next fill because the participant attempted to receive an early refill. The physician might not have chosen to call for a prior authorization and simply allowed the therapy to terminate because the prescription was no longer necessary. There might have been no follow up prescription filled because the member was no longer eligible for Medicaid.

Second, some delays seen through the prescription claims data are not actually delays in therapy. The physician may have given the recipient prescription samples. Although a delay in the payment for a claim is quantifiable, it is difficult to truly quantify an actual delay in therapy from claims data. A pharmacist may choose to dispense a small supply of denied medication for a recipient until such time that the prescriber requests a prior authorization for the product.

Nevertheless, although it is desirable to increase the share of "preferred" medications versus "nonpreferred" medications, when claims are denied, it is important to enable

12/20/2005 Page 33 of 69

participants who need prescribed medications to obtain them while limiting inappropriate use of medications. Therefore, ACS performed an analysis to determine if the implementation of the Indiana State Medicaid Preferred Drug List (PDL) Program impacted medication access for participants.

Report 1 Review

ACS' claims processing system enabled the identification of denied claims for nonpreferred medications in the preferred drug list. Of the 188,508 monthly recipients followed between May and September 2003, only 4,462 (2.36%) experienced a denied pharmacy claim. Most of these recipients went on to receive the medication through a prior authorization approval. Over half of the follow-up claims were processed on the same day that the denial occurred. Therefore, delays in obtaining medications were a problem for only 1.2% of recipients. Of those recipients experiencing a delay, only 1,485 (0.78%) overall and 0.3% recipients receiving prescriptions for antihypertensives experienced a denied claim with no prior approval of a nonpreferred medication, and no paid claim for a related medication within 30 days. The percent of eligible participants experiencing an exception event, and not receiving a medication within 30 days of the event, ranged from 0.3% for the antihypertensive classes

Further, denials for a given class diminished monthly as providers gained experience with the program. It is impossible to know from pharmacy claims data what portion of these dropped claims were clinically inappropriate to be getting filled anyway, such as duplicate or unnecessary therapies. Overall, the low percentage suggests a minimum impact on PDL users. We do not know how many of the dropped claims were due to medications having no refills left as opposed to being new medications with refills left. While we understand that some dropped claims may have come from medications with no refills, this analysis was not included in the study.

Therapy termination was an expected and potentially desirable outcome for the preferred drug list program. The PDL intervention was helpful in flagging cases of inappropriate therapy or therapy that was due to be discontinued. Therefore, some share of those exception events that were without follow up would be appropriate. Again, it was not possible to assess the degree to which exception events with no follow up medication were desirable or were instead the result of recipients, physicians or pharmacists who failed to follow through with their respective responsibilities.

Report 2 Review

Since between 30 to 50% of all patients fail to follow their prescribed therapy²¹ once they receive it, noncompliance or lack of persistence with taking medications may be a larger concern. Therefore, Report 2 analysis examined recipients who were noncompliant (as

12/20/2005 Page 34 of 69

²¹ Amercian Medical Association – Report 2 of the Council on Scientific Affairs, 1998.

evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

Methods

For the purposes of studying noncompliance, recipients were classified as follows. Recipients were followed from March 2002 to September 2004. The Indiana Medicaid recipients had an overall rate of noncompliance of 26.4%.

Table 2.1. Sample Sizes

		Value Label					
Persistence	20	No Change, PDL to PDL, Persistent Tx	7198				
	21	NonPDL to PDL Change, Persistent PDL Therapy	4259				
	30	No Change, Mild NonCompliance	747				
	31	NonPDL to PDL Change w/ Mild NonCompliance	400				
	90	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	1820				
	91	NonPDL to PDL change, Severely not persistent with PDL med	1150				

Results

Results showed that even recipients who were classified as "mildly non-compliant" with their medications (defined as recipients who missed at least 2 prescriptions of 30-day therapy in the past 12 months) were significantly different from recipients who persisted with their therapy. Results also demonstrated that there were no significant differences in whether recipients were previously taking nonpreferred and switched to preferred medications or had been on preferred medications all along (see Chapter 3); however, there were significant differences between recipients who were persistent in taking their therapy and those who were noncompliant (see Table 2.2).

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were noncompliant (Table 2.3).

Conclusions

In conclusion, the results help illustrate that health outcomes for Indiana Medicaid recipients are less likely to be related to whether recipients are taking nonpreferred or preferred medications, but rather whether recipients will be compliant with taking any medication, be it preferred or nonpreferred.

Table 2.2. MANOVA on Compliance

Tests of Between-Subjects Effects

		Type III Sum of					Partial Eta	Noncent.	Observed
Source	Dependent Varial		df	Mean Square	F	Sig.	Squared	Parameter	Power
Corrected Mod	MDPaid	183564588.631 ^b	6	30594098.105	49.516	.000	.019	297.097	1.000
	ERPaid	11535275.434°	6	1922545.906	31.668	.000	.012	190.009	1.000
	LabPaid	2846671.162 ^d	6	474445.194	6.139	.000	.002	36.835	.999
	TotalMedPaid	4778083957.148 ^e	6	796347326.191	3.805	.001	.001	22.829	.967
Intercept	MDPaid	1378533125.074	1	1378533125.074	231.140	.000	.125	2231.140	1.000
	ERPaid	65993909.268	1	65993909.268	087.053	.000	.065	1087.053	1.000
	LabPaid	83322469.486	1	83322469.486	078.157	.000	.065	1078.157	1.000
	TotalMedPaid	18374986587.559	1	8374986587.559	708.928	.000	.044	708.928	1.000
TheraClass6	MDPaid	14229582.985	1	14229582.985	23.030	.000	.001	23.030	.998
	ERPaid	1413640.418	1	1413640.418	23.286	.000	.001	23.286	.998
	LabPaid	407434.193	1	407434.193	5.272	.022	.000	5.272	.632
	TotalMedPaid	3681841761.124	1	3681841761.124	17.592	.000	.001	17.592	.987
Persistence	MDPaid	168307855.953	5	33661571.191	54.481	.000	.017	272.404	1.000
	ERPaid	10159820.566	5	2031964.113	33.471	.000	.011	167.353	1.000
	LabPaid	2552353.979	5	510470.796	6.605	.000	.002	33.026	.998
	TotalMedPaid	1536695422.945	5	307339084.589	1.468	.196	.000	7.342	.523
Error	MDPaid	9618232713.298	15567	617860.391					
	ERPaid	945057151.904	15567	60709.010					
	LabPaid	1203054332.983	15567	77282.349					
	TotalMedPaid	8093409022.856	15567	209294880.775					
Total	MDPaid	15509128875.966	15574						
	ERPaid	1229793262.391	15574						
	LabPaid	1587271882.389	15574						
	TotalMedPaid	6005304751.637	15574						
Corrected Total	MDPaid	9801797301.929	15573						
	ERPaid	956592427.338	15573						
	LabPaid	1205901004.145	15573						
	TotalMedPaid	2871492980.004	15573						

a. Computed using alpha = .05

 $b \cdot R$ Squared = .019 (Adjusted R Squared = .018)

c.R Squared = .012 (Adjusted R Squared = .012)

d.R Squared = .002 (Adjusted R Squared = .002)

e.R Squared = .001 (Adjusted R Squared = .001)

Table 2.3 Mean Differences Recipients who fill their medication persistently (Persistent Users) and those who are inconsistent in getting their medications filled (NonCompliant)

Descriptive Statistics

	Persistence	Mean	Std. Deviation	N
MDPaid	No Change, PDL to PDL, Persistent Tx	\$553.7238	\$705.03821	7198
	NonPDL to PDL Change, Persistent PDL Therapy	\$525.7069	\$671.53462	4259
	No Change, Mild NonCompliance	\$781.7323	\$955.08008	747
	NonPDL to PDL Change w/ Mild NonCompliance	\$791.5029	\$966.33998	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	\$768.2491	\$1,023.73542	1820
	NonPDL to PDL change, Severely not persistent with PDL med	\$786.5029	\$1,011.40274	1150
	Total	\$605.3638	\$793.35345	15574
ERPaid	No Change, PDL to PDL, Persistent Tx	\$118.3292	\$223.65162	7198
	NonPDL to PDL Change, Persistent PDL Therapy	\$115.6212	\$237.21147	4259
	No Change, Mild NonCompliance	\$181.8547	\$299.40468	747
	NonPDL to PDL Change w/ Mild NonCompliance	\$190.2817	\$329.01114	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	\$169.8271	\$273.71790	1820
	NonPDL to PDL change, Severely not persistent with PDL med	\$171.7533	\$295.80007	1150
	Total	\$132.4466	\$247.84338	15574
LabPaid	No Change, PDL to PDL, Persistent Tx	\$149.1504	\$253.69882	7198
	NonPDL to PDL Change, Persistent PDL Therapy	\$149.8065	\$244.64870	4259
	No Change, Mild NonCompliance	\$180.1872	\$365.92513	747
	NonPDL to PDL Change w/ Mild NonCompliance	\$180.2543	\$286.57844	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	\$167.6293	\$356.60837	1820
	NonPDL to PDL change, Severely not persistent with PDL med	\$185.8309	\$325.05760	1150
	Total	\$156.4853	\$278.27211	15574
TotalMedPaid	No Change, PDL to PDL, Persistent Tx	\$7,490.3659	\$14,977.11166	7198
	NonPDL to PDL Change, Persistent PDL Therapy	\$7,652.3951	\$14,969.60032	4259
	No Change, Mild NonCompliance	\$7,410.1710	\$11,868.95631	747
	NonPDL to PDL Change w/ Mild NonCompliance	\$6,702.5388	\$8,601.26253	400
	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	\$8,170.2209	\$14,749.93520	1820
	NonPDL to PDL change, Severely not persistent with PDL med	\$7,829.7778	\$11,905.69271	1150
	Total	\$7,615.1062	\$14,474.84237	15574

Report 3 Review

For Report 3, the PDL program's impact on users' access to medications after the PDL program had been operating for some length of time was assessed. ACS' claims processing system enabled the identification of denied claims for nonpreferred medications in the preferred drug list. Retail pharmacy prescription claims were examined at 26 and 31 months after initial implementation. Since pharmacy claims for recipients residing in nursing homes were many times billed months after the date of service, only outpatient retail pharmacy claims conducted at point-of-sale were analyzed. Of the 203,463 monthly recipients followed for 26-months after the PDL program began, and of the 208,693 monthly recipients followed for 31-months after the initial PDL program began, only 3,288 (1.5%) experienced a denied claim in the two months of October 1, 2004 and March 31, 2005.

A random sample of 1,000 retail pharmacy Medicaid recipients' claims were analyzed during the month of October 2004 after the recipient experienced a denied claim due to a non-PDL prescription claim. Another random sample of 750 were analyzed in the month of March 2005. Of the 1,750 random recipients followed from the initial claim rejection due to a non-PDL prescription claim, only 47 recipients (0.023%) in October 2004 and 28 recipients (0.013%) in March 2005 experienced a denied claim with no paid claim for a related medication within the next 30 days.

It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. Claims data does not allow full explanation for the therapy interruptions. For example, there are many potential reasons other than PDL such as: physician sampling of medications, other 3rd party liability, patient compliance, or changes in patient therapy.

The denied claims were primarily antihypertensive medications, especially Angiotensin Receptor Blockers (ARBs) and ACE Inhibitors. Based upon the pattern that ACS observed as developing after the criteria were implemented, it appears that some providers may have been attempting to bypass the intent of the Indiana criteria instituted. For example:

- When eye drop claims denied, a pattern revealed some pharmacy providers resubmitted with an emergency override code and input 3-days as the days supply. This pattern allowed the claim to process and pay; thereby, bypassing the edit criteria.
- When there was a denial for step therapy for ARBs where recipients
 must have failed an ACE Inhibitor first, a pattern revealed some
 providers switched the claim from plain ARBs to combination ARBs
 with HCTZ that had no step therapy criteria. This immediate switch
 allowed the claim to process and pay; thereby, bypassing the edit
 criteria.

12/20/2005 Page 38 of 69

Overall, the initial number (0.78% without a related claim within 30 days of the denial in the first year) suggest a minimum impact on PDL users. Further, denials for a given class diminished monthly as providers gained experience with the program as evidenced by the 0.023% at 26 months and 0.013% at 31 months after the program began.

To put this into perspective, the rate of nonpreferred claims denials where recipients had no later related claim within the next 30 days is far lower than the 30 to 50% noncompliance rate documented in the literature. Since between 30 to 50% of all patients fail to follow their prescribed therapy once they receive it, noncompliance or lack of persistence with taking medications may be a larger concern.

CHAPTER 3 PREFERRED DRUG LIST PROGRAM PRIOR AUTHORIZATIONS

Preferred Drug List (PDL) program prior authorizations (PA's) requested, approved, and denied are listed in the table below. In order to give two different perspectives on the PA's requested for non-preferred drugs, both calendar year and federal fiscal year figures are listed along with partial year data.

During the calendar year 2003 (1/1/03 to 12/31/03) there were 73,251 PDL program prior authorizations requested. Of the 73,251 PA's requested, 71,053 were approved (97.0%), 259 were denied (0.4%) and 1,939 were suspended (2.6%).

During the calendar year 2004 (1/1/04 to 12/31/04) there were 81,440 PDL program prior authorizations requested. Of the 81,440 PA's requested, 79,567 were approved (97.7%), 1,352 were denied (1.7%) and 521 were suspended (0.2%).

The percentage of prior authorizations (PA's) for non-preferred drugs that were approved slightly decreased from 99.5% (between August 2002 to December 2002 when the PDL program first began) to it lowest point of 97.0% in calendar year 2003. The percentage of PA's for non-preferred drugs that were approved increased from it lowest point in calendar year 2003 (97.0%) through calendar year 2004 (97.7%) and into the first quarter 2005 (98.2%).

The percentage of prior authorizations (PA's) for non-preferred drugs that were denied slightly increased over the life of the PDL Program from 0.2% denied (between August 2002 to December 2002 when the PDL program first began) to 1.3% in the first quarter 2005.

Table 3.1. Preferred Drug List Prior Authorizations

Time Period	Average # Utilizers per Month	Total All PA's Requested	Approved	% A	# A PUPM	De- nied	% D	Sus- pend ed	% S
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	204,840	80,950	79,200	97.8%	0.0322	193	0.2%	1,557	1.9%
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	208,995	75,705	73,681	97.3%	0.0294	1,177	1.6%	847	1.1%
Oct 1, 2004 to Mar 31, 2005 (First 6-months of FFY 2005)	205,982	41,052	40,427	98.5%	0.0327	513	1.2%	112	0.3%
Aug 1, 2002 to Dec 31, 2002	200,054	17,866	17,775	99.5%	0.022	91	0.5%	0	0%
Calendar Year 2003	207,593	73,251	71,053	97.0%	0.029	259	0.4%	1,939	2.6%
Calendar Year 2004	204,754	81,440	79,567	97.7%	0.032	1,352	1.7%	521	0.6%
Jan 1, 2005 to Jun 30, 2005	200,134	34,009	33,481	98.4%	0.028	456	1.3%	72	0.2%

12/20/2005 Page 40 of 69

TABLE 3.2

NUMBER OF PRIOR AUTHORIZATIONS ISSUED BETWEEN AUGUST 2002 AND DECEMBER 2002 BY THERAPEUTIC CLASSES WITH PREFERRED DRUG LISTS IN EFFECT AT THE TIME WITH COUNT OF DENIALS

	Count of PAs		
	Between August	Count of	
	and December	<u>Denied</u>	
PDL Therapeutic Class	2002	<u>PAs</u>	% Denied
	1		0.0%
A4D - ACE Inhibitor	594		0.0%
A4D - ACE Inhibitor W/Diuretics	2		0.0%
A4F - Angiotensin Receptor Blockers	1		0.0%
A4F - Angiotensin Receptor Blockers w/Diuretics	5		0.0%
A4K - ACE Inhibitor w/CCB	16		0.0%
A9A - Calcium Channel Blockers	71		0.0%
C4N - Thiazolidenediones	16		0.0%
D4K - Proton Pump Inhibitors	13,289	90	0.7%
H3F - Triptans	29		0.0%
J5D - Beta Agonists	258	1	0.4%
J7A/B/C - ALPHA/BETA Adrenergic Blockers	1,790		0.0%
M4E - Statins	9		0.0%
M9P - Platelet Aggregation Inhibitors	84		0.0%
P5A - Inhaled Glucocorticoids	97		0.0%
R1M - LOOP Diuretics	22		0.0%
Z2A - Non-Sedating Antihistamines	1,491		0.0%
TOTAL	17,775	91	0.5%

12/20/2005 Page 41 of 69

Table 3.3 Calendar Year 2003 PA's Related to the PDL Program



Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: Client ID: 5/14/2004 INCAID

From 01/01/2003 To 12/31/2003

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	594	1	Ü
ACEI with CCB	191	'	
ACEI with Diuretics	30		
Angiotensin Receptor Blockers (ARBs)	3.824	5	2
Antidiabetic Agents	672	1	
Antiemetic - Antivertigo Agents	66		
Antifungal Oral	848	1	
Antifungal Topicals	602	'	
Antipsoriatics	3		
Antiulcer- H Pyloric Agents	168		
Antiviral Anti-herpetic Agents	148		
Antiviral Influenza Agents	429		
ARBs with Diuretics	243	2	1
Beta Adrenergic Blockers	211		<u> </u>
Bile Acid Sequestrants	146	2	
Brand Name Narcotics	466	1	
Brand NSAIDS	6,493	61	992
Calcium Channel Blockers	284		
Cephalosporins	482		
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	40		
Duragesic	2.315	4	18
Fibric Acids	84		
Fluoroquinolones	402		
Forteo	59	2	
H2 Antagonists	2,464	11	183
Heparin and Related Products	4		
HMG CoA Reductase Inhibitors	631	2	
Imitrex Tablets Month Limit	51		
Inhaled Glucocorticoids	1,026		
Leukocyte Stimulants	18		
Leukotriene Receptor Antagonists	24		
Long Acting Beta Agonists	239	1	
Loop Diuretics	21		
Macrolides	276		1
Miotics - OIPR	94		
Non-Sedating Antihistamines	1,789	4	
Ophthalmic Antibiotics	368		
Opthalmic Mast Cell Stabilizers	89	1	
Oral Antifungals	49	1	
Otic Antibiotics	55		
Oxycodone and Hydrocodone APAP	145	23	12
Oxycodone IR	109	1	4
Oxycontin	797	2	16
Platelet Aggregation Inhibitors	143		
PROPOXYPHENE WITH APAP	24		
Proton Pump Inhibitors	15,632	12	13
SERMS - Bone Resorption Agents	943	3	2



Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date:

5/14/2004

From 01/01/2003 To 12/31/2003

Short Acting Beta Agonists	3,049	3	1
Skeletal Muscle Relaxants	945	1	
Smoking Deterrent Agents	73		
Systemic Vitamin A Derivatives	164		
Thiazolidenediones	1,207		3
Triptans	449		
Ultram and Ultracet	1,242	18	137
Urinary Tract Antispasmodics- Antiincontinence	271		
Vaginal Antimicrobials	736	2	
Zithromax Limit - PDLZPAK	112		
Zofran Tablet Limit (10 tablets per Rx)	15		
Sum:	52,054	165	1,385

Table 3.4 Calendar Year 2004 PA's Related to PDL Program



Indiana Medicaid - Preferred Drug List Prior Authorizations

 Key: A=Approved
 D=Denied
 S=Suspended
 Run Date:
 3/31/2005

 Client ID:
 INCAID

From 01/01/2004 To 12/31/2004

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	1,469	15	1
ACEI with CCB	105	1	0
ACEI with Diuretics	130	1	0
Acne Agents	7	0	0
Actiq	58	40	0
Agents to treat COPD	28	0	0
Alpha Adrenergic Blockers	75	1	0
Alpha- Beta Adrenergic Blockers	1,248	6	10
Angiotensin Receptor Blockers (ARBs)	4,212	26	31
Antidiabetic Agents	535	3	4
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	812	1	1
Antifungal Topicals	555	4	1
_ ·	11	0	0
Antipsoriatics	376	2	3
Antiulcer- H Pyloric Agents	442	1	3
Antiviral Anti-herpetic Agents	151	1	0
Antiviral Influenza Agents	198	0	2
ARBs with Diuretics	196	0	0
Benign Prostatic Hypertrophy		_	-
Beta Adrenergic Blockers	170	1	0
Beta Adrenergics & Corticosteroids	1,119	1	1
Bile Acid Sequestrants	242	1	0
Bone Formation Stimulating	111	2	0
Brand NSAIDS	1,275	132	157
Calcium Channel Blockers	345	3	0
Calcium Channel Blockers w/HMG CoA Reductase Inh	1	0	0
Carafate (Sucralfate)	197	78	10
Cephalosporins	557	7	1
Cox-2 Inhibitor	6,655	599	86
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	2	0	0
Duragesic	308	0	0
Eye Antibiotic- Corticosteroid Combo	307	4	1
Eye Antihistamines	386	5	1
Fibric Acids	977	0	0
Fluoroquinolones	278	1	0
Forteo	136	12	0
Growth Hormones	298	44	6
H2 Antagonists	4	0	0
Hematinics	12	0	0
Heparin and Related Products	27	0	0
HMG CoA Reductase Inhibitors	857	4	6
Imitrex Stat Dose Month Limit	1	0	0
Imitrex Tablets Month Limit	4	0	0
Inhaled Glucocorticoids	641	2	1
Inspra	3	0	0

Page 1 of 2

Page 44 of 69

Table 3.4 -- continued --



Indiana Medicaid - Preferred Drug List Prior Authorizations

3/31/2005 Run Date: C S Client ID: INCAID From 01/01/2004 To 12/31/2004 Ketolides 10 Lactulose Leukocyte Stimulants 35 0 0 3.356 9 10 Leukotriene Receptor Antagonists Long Acting Beta Agonists 176 0 Loop Diuretics 97 0 Macrolides 169 0 Miotics - OIPR 474 Narcotics 1.348 24 3 5 Nasal Steroids and Antihistamines 609 0 Non-Sedating Antihistamines Ophthalmic Antibiotics 6,680 68 25 474 0 0 Opthalmic Mast Cell Stabilizers 70 Oral Antifungals 18 0 0 0 0 Other Lipotropics Otic Antibiotics 350 Oxycodone and Hydrocodone APAP 10 Oxycodone IR 0 0 119 0 Oxycontin 7,019 49 Plan Limits 21 Platelet Aggregation Inhibitors Prior Authorization 40 PROPOXYPHENE WITH APAP 0 22,895 Proton Pump Inhibitors SERMS - Bone Resorption Agents 126 103 874 0 2,437 Short Acting Beta Agonists Skeletal Muscle Relaxants 1,538 12 8 Smoking Deterrent Agents 41 0 0 Stadol- NS 5 38 0 0 Systemic Vitamin A Derivatives Thiazolidenediones 1,934 18 Topical Estrogen Agents 156 237 0 Topical Vitamin A Derivatives 0 332 TPL Claim Too Old TPL Within Filing Limit 0 415 Triptans Ultracet 1 0 0 Ultram and Ultracet 0 0 442 Urinary Tract Antispasmodics- Antiincontinence Vaginal Antimicrobials Zithromax Limit - PDLZPAK 12 Zofran Tablet Limit (10 tablets per Rx) 0 0

Page 2 of 2

Page 45 of 69

521

Sum:

79,567

1,352

Table 3.5 First-Half Year 2005 (January 1, 2005 to June 30, 2005) PA's Related to PDL Program



Indiana Medicaid - Preferred Drug List Prior Authorizations

 Key: A=Approved
 D=Denied
 S=Suspended
 Run Date:
 8/26/2005

 From 01/01/2005
 To 06/30/2005
 Client ID:
 INCAID

F10III 01/01/2005 10 00/30/2005		Gliefic ID.	IIIOAID
Therapeutic Glass or Preferred Drug Description	A	D	S
ACE Inhibitors	456	0	2
A CEI with CCB	26	2	0
ACEI with Diuretics	41	0	1
A cne Agents	139	0	0
Actiq	52	6	0
Agents to treat COPD	410	1	0
Alpha Adrenergic Blockers	б	0	0
Alpha- Beta Adrenergic Blockers	1,053	1	4
Angiotensin Receptor Blockers (ARBs)	2,042	3	6
Antidiabetic Agents	434	0	2
Antiemetic - Antivertigo Agents	52	0	0
Antifungal Oral	401	0	0
Antifungal Topicals	196	2	0
Antipsoriatics	3	0	0
Antiulcer- H Pyloric Agents	140	0	1
Antiviral Anti-herpetic Agents	262	1	0
Antiviral Influenza Agents	9	0	0
ARBs with Diuretics	110	1	0
Benign Prostatic Hypertrophy	39	0	0
Beta Adrenergic Blockers	45	0	0
Beta Adrenergics & Corticosteroids	449	0	2
Bile Acid Sequestrants	110	0	0
Bone Formation Stimulating	179	0	1
Brand NSAIDS	451	191	2
Galcium Channel Blockers	174	0	1
Galcium Channel Blockers w/HM G GoA Reductase Inh	2	0	0
Caratate (Sucraitate)	43	43	0
Cephalosporins	229	1	0
Cox-2 Inhibitor	1,692	136	5
Eye Antibiotic- Corticosteroid Combo	164	1	0
Eye Antihistamines	96	1	0
Fibric Acids	257	0	0
Fluoroquinolones	119	0	1
Forteo	90	14	0
Growth Hormones	139	11	2
H2 Antagonists	7	0	0
Hematinics	1	0	0
Heparin and Related Products	11	0	0
HMG CoA Reductase Inhibitors	115	0	0
Inhaled Glucocorticoids	10	0	0
Inspra	17	0	0
Ketolides	156	0	0
Leukocyte Stimulants	13	0	0
Leukotriene Receptor Antagonists	703	1	1
Long Acting Beta Agonists	12	1	0
Loop Diuretics	20	0	0

Page 1 of 2

Table 3.5 -- continued --



Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 8/26/2005

From 01/01/2005 To 06/30/2005		Client ID:	INGAID
Therapeutic Class or Preferred Drug Description	Α	D	S
Macrolides	75	0	0
Miotics - OIPR	166	0	1
Narcotics	550	3	0
Nasal Steroids and Antihistamines	519	2	1
Non-Sedating Antihistamines	3,202	6	6
Ophthalmic Antibiotics	79	0	1
Opthalmic Mast Gell Stabilizers	17	0	0
Other Lipotropics	357	0	0
Otic Antibiotics	47	0	0
Plan Limits	4,412	6	12
Platelet Aggregation Inhibitors	63	0	0
Proton Pump Inhibitors	9,267	16	15
SERMS - Bone Resorption Agents	476	1	1
Short Acting Beta Agonists	545	0	0
Skeletal Muscle Relaxants	665	2	2
Smoking Deterrent Agents	3	0	0
Systemic Vitamin A Derivatives	1	0	0
Thiazolidenediones	626	1	0
Topical Estrogen Agents	37	0	0
Topical Vitamin A Derivatives	66	0	0
TPL Claim Too Old	5	0	0
TPL Within Filing Limit	45	0	0
Triptans	113	0	0
Urinary Tract Antispasmodics- Antiincontinence	269	0	0
Vaginal Antimicrobials	413	0	0
Sum:	33,481	456	72

Page 2 of 2

Table 3.6 Federal Fiscal Year 2003 PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior Authorizations			
A C S Key: A=Approved D=Denied S=Suspend	led	Run Date:	3/31/2005
From 10/01/2002 To 09/30/2003		Olicin ID.	
Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	750	0	1
ACEI with CCB	160	0	0
ACEI with Diuretics	20	0	0
Alpha Adrenergic Blockers	7	0	0
Angiotensin Receptor Blockers (ARBs)	3,238	4	2
Antidiabetic Agents	509	1	0
Antiemetic - Antivertigo Agents	41	0	0
Antifungal Oral	693	1 1	0
Antifungal Topicals	309	0	0
Antipsoriatics	1	0	0
Antiulcer- H Pyloric Agents	54	0	0
Antiviral Anti-herpetic Agents	24	0	0
Antiviral Influenza Agents	3	0	0
	191	2	2
ARBs with Diuretics	1,976	0	0
Beta Adrenergic Blockers	112	1	0
Bile Acid Sequestrants	1110		-
Brand NSAIDS	5,993	47	708
Calcium Channel Blockers	270	0	0
Carafate (Sucralfate)	223	36	56
Cephalosporins	334	0	0
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	36	0	0
Duragesic	2,040	4	18
Fibric Acids	25	0	0
Fluoroquinolones	318	0	0
Forteo	31	0	0
Growth Hormones	271	0	12
H2 Antagonists	2,770	10	183
Heparin and Related Products	1	0	0
HMG CoA Reductase Inhibitors	511	0	0
Imitrex Stat Dose Month Limit	16	0	0
Imitrex Tablets Month Limit	40	0	0
Inhaled Glucocorticoids	871	0	0
Lactulose	511	5	102
Leukocyte Stimulants	10	0	0
Leukotriene Receptor Antagonists	7	0	0
	202	1	0
Long Acting Beta Agonists		0	0
Loop Diuretics	26	_	
Macrolides	242 57	0	0
Miotics - OIPR		_	
Narcotics	374	0	0
Nasal Steroids and Antihistamines	1	0	0
Non-Sedating Antihistamines	1,979	0	0
Ophthalmic Antibiotics	178	0	0
Opthalmic Mast Cell Stabilizers	31	0	0
Oral Antifungals	12	0	0

Page 1 of 2

Table 3.6 -- continued --



Indiana Medicaid - Preferred Drug List Prior Authorizations

		•	
S		Run Date:	3/31/2005
	40/04/0000 T 00/00/0000	Client ID:	INCAID

Otic Antibiotics 21 0 0 Oxycodone and Hydrocodone APAP 1444 23 12 Oxycodone IR 134 1 4 Oxycontin 674 2 16 Platelet Aggregation Inhibitors 169 0 0 Prior Authorization 36,827 22 283 PROPOXYPHENE WITH APAP 20 0 0 Proton Pump Inhibitors 8,358 10 13 SERMS - Bone Resorption Agents 780 1 2 Short Acting Beta Agonists 2,452 3 1 Skeletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultracet 1,5607	110111 10/01/2002 10 03/30/2003			
Oxycodone IR 134 1 4 Oxycontin 674 2 16 Platelet Aggregation Inhibitors 169 0 0 Prior Authorization 36,827 22 283 PROPOXYPHENE WITH APAP 20 0 0 Proton Pump Inhibitors 8,358 10 13 SERMS - Bone Resorption Agents 780 1 2 Short Acting Beta Agonists 2,452 3 1 Skeletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobi	Otic Antibiotics	21	0	0
Oxycontin 674 2 16 Platelet Aggregation Inhibitors 169 0 0 Prior Authorization 36,827 22 283 PROPOXYPHENE WITH APAP 20 0 0 Proton Pump Inhibitors 8,358 10 13 SERMS - Bone Resorption Agents 780 1 2 Short Acting Beta Agonists 2,452 3 1 Skeletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax	Oxycodone and Hydrocodone APAP	144	23	12
Platelet Aggregation Inhibitors 169 0 0 Prior Authorization 36,827 22 283 PROPOXYPHENE WITH APAP 20 0 0 Proton Pump Inhibitors 8,358 10 13 SERMS - Bone Resorption Agents 780 1 2 Short Acting Beta Agonists 2,452 3 1 Skeletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0	Oxycodone IR	134	1	4
Prior Authorization 36,827 22 283 PROPOXYPHENE WITH APAP 20 0 0 Proton Pump Inhibitors 8,358 10 13 SERMS - Bone Resorption Agents 780 1 2 Short Acting Beta Agonists 2,452 3 1 Skoletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zofran Tablet Limit (10 tablets per Rx) 10 0	Oxycontin	674	2	16
PROPOXYPHENE WITH APAP 20 0 0 Proton Pump Inhibitors 8,358 10 13 SERMS - Bone Resorption Agents 780 1 2 Short Acting Bota Agonists 2,452 3 1 Skeletal Muscle Relaxants 7114 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0	Platelet Aggregation Inhibitors	169	0	0
Proton Pump Inhibitors	Prior Authorization	36,827	22	283
SERMS - Bone Resorption Agents 780 1 2 Short Acting Beta Agonists 2,452 3 1 Skeletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0	PROPOXYPHENE WITH APAP	20	0	0
Short Acting Beta Agonists 2,452 3 1 Skeletal Muscle Relaxants 714 0 0 Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0 0	Proton Pump Inhibitors	8,358	10	13
Skeletal Muscle Relaxants	SERMS - Bone Resorption Agents	780	1	2
Smoking Deterrent Agents 66 0 0 Stadol- NS 44 0 3 Systemic Vitamin A Derivatives 84 0 0 Thiazolidenediones 684 0 2 Triptans 369 0 0 Ultracet 14 0 0 Ultram and Ultracet 1,607 18 137 Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0 0	Short Acting Beta Agonists	2,452	3	1
Stadol- NS	Skeletal Muscle Relaxants	714	0	0
Systemic Vitamin A Derivatives	Smoking Deterrent Agents	66	0	0
Thiazolidenediones 684 0 2	Stadol- NS	44	0	3
Triptans 369 0 0	Systemic Vitamin A Derivatives	84	0	0
Ultracet	Thiazolidenediones	684	0	2
Ultram and Ultracet	Triptans	369	0	0
Urinary Tract Antispasmodics- Antiincontinence 209 0 0 Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0 0	Ultracet	14	0	0
Vaginal Antimicrobials 280 1 0 Zithromax Limit - PDLZPAK 72 0 0 Zofran Tablet Limit (10 tablets per Rx) 10 0 0	Ultram and Ultracet	1,607	18	137
Tithromax Limit - PDLPAK 72 0 0	Urinary Tract Antispasmodics- Antiincontinence	209	0	0
Zofran Tablet Limit (10 tablets per Rx) 10 0	Vaginal Antimicrobials	280	1	0
Zerran Paret Zimit (10 tableto per 114)	Zithromax Limit - PDLZPAK	72	0	0
Sum: 79,200 193 1,557	Zofran Tablet Limit (10 tablets per Rx)	10	0	0
	Sum:	79,200	193	1,557

Table 3.7 Federal Fiscal Year 2004 PA's Related to PDL Program



From 10/01/2003 To 09/30/2004

FIORI 10/01/2003 10 09/30/2004			
Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	1,325	16	1
ACEI with CCB	126	1	0
ACEI with Diuretics	104	1	0
Actiq	32	40	0
Alpha Adrenergic Blockers	67	1	0
Alpha- Beta Adrenergic Blockers	931	6	9
Angiotensin Receptor Blockers (ARBs)	3,642	25	28
Antidiabetic Agents	513	2	3
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	768	1	1
Antifungal Topicals	741	4	0
Antipsoriatics	10	0	0
Antiulcer- H Pyloric Agents	414	2	2
Antiviral Anti-herpetic Agents	433	1	2
Antiviral Influenza Agents	546	1	0
ARBs with Diuretics	204	0	1
Benign Prostatic Hypertrophy	18	0	0
Beta Adrenergic Blockers	131	1	0
Beta Adrenergics & Corticosteroids	829	1	1
Bile Acid Sequestrants	182	2	0
Bone Formation Stimulating	73	2	0
Brand NSAIDS	2,375	92	443
Calcium Channel Blockers	351	3	0
Carafate (Sucralfate)	197	82	26
Cephalosporins	553	5	0
Cox-2 Inhibitor	4,687	488	77
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	6	0	0
Duragesic	919	1	0
Eye Antibiotic- Corticosteroid Combo	204	4	1
Eye Antihistamines	242	4	1
Fibric Acids	921	0	0
Fluoroquinolones	295	1	0
Forteo	113	11	0
Growth Hormones	289	32	8
H2 Antagonists	3	1	0
Hematinics	13	0	0
Heparin and Related Products	22	0	0
HMG CoA Reductase Inhibitors	820	6	7
Imitrex Stat Dose Month Limit	6	0	0
Imitrex Tablets Month Limit	15	0	0
Inhaled Glucocorticoids	861	2	1
Lactulose	96	1	26
Leukocyte Stimulants	33	0	0
Leukotriene Receptor Antagonists	2,788	8	10
Long Acting Beta Agonists	209	1	0

Page 1 of 2

Page 50 of 69

Client ID: INCAID

Table 3.7 -- continued --



Indiana Medicaid - Preferred Drug List Prior Authorizations

3/2/2005 Run Date: C S INCAID Client ID: From 10/01/2003 To 09/30/2004 Loop Diuretics Macrolides 147 Miotics - OIPR 356 0 0 1,110 23 Narcotics 3 Nasal Steroids and Antihistamines Non-Sedating Antihistamines 262 0 4,868 67 24 Ophthalmic Antibiotics 592 Opthalmic Mast Cell Stabilizers Oral Antifungals 119 55 307 0 Otic Antibiotics 0 50 Oxycodone and Hydrocodone APAP Oxycodone IR 0 7 0 Oxycontin Plan Limits 5,244 44 Platelet Aggregation Inhibitors
Prior Authorization 223 113 PROPOXYPHENE WITH APAP 5 22.830 1 119 Proton Pump Inhibitors SERMS - Bone Resorption Agents 124 809 4 0 2,723 Short Acting Beta Agonists Skeletal Muscle Relaxants 12 1,360 Smoking Deterrent Agents 43 0 0 3 116 0 0 Systemic Vitamin A Derivatives Thiazolidenediones 2,013 14 Topical Estrogen Agents 116 Topical Vitamin A Derivatives 164 0 447 Triptans Ultracet Ultram and Ultracet 0 Urinary Tract Antispasmodics- Antiincontinence 371 3 0 Vaginal Antimicrobials Zithromax Limit - PDLZPAK 1,510 8 52 Zofran Tablet Limit (10 tablets per Rx) 0 0 Sum: 73,681 847 1,177

Table 3.8 Partial Federal Fiscal Year 2005 PA's Related to PDL Program

Indiana Medicaid - Preferred Drug List Prior	Authoria	zations	
A C S Key: A=Approved D=Denied S=Suspended	1	Run Date:	7/11/2005
From 10/01/2004 To 03/31/2005	J	Client ID:	INGAID
Therapeutic Class or Preferred Drug Description	Α	D	S
A CE Inhibitors	624	0	1
ACEI with CCB	43	2	0
A CEI with Diuretics	61	0	2
Acne Agents	70	0	0
Actiq	47	4	0
Agents to treat COPD	244	0	0
Alpha Adrenergic Blockers	20	0	0
Alpha- Beta Adrenergic Blockers	723	0	3
Angiotensin Receptor Blockers (ARBs)	2,052	5	12
Antidiabetic Agents	490	1	2
Antiemetic - Antivertigo Agents	54	Ö	0
Antifungal Oral	376	Ö	0
Antirungal Topicals	209	1	1
Antipsoriatics	5	Ö	Ö
Antiulcer- H Pyloric Agents	150	Ö	2
Antiviral Anti-herpetic Agents	290	1	1
Antiviral Influenza Agents	38	ö	Ö
ARBs with Diuretics	105	0	1
	57	0	0
Benign Prostatic Hypertrophy Beta Adrenergic Blockers	61	0	0
Beta Adrenergic Brockers Beta Adrenergics & Corticosteroids	452	0	1
	150	0	0
Bile Acid Sequestrants	157	0	1
Bone Formation Stimulating	471	160	2
Brand NSAIDS	17.1	0	0
Calcium Channel Blockers	2	0	0
Calcium Channel Blockers w/HM G CoA Reductase Inh	77	37	0
Caratate (Sucrattate)			
Cephalosporins	280	3	1
Cox-2 Inhibitor	2,761	197	14
Eye Antibiotic- Corticosteroid Combo	188	0	0
Eye Antihistamines	190	2	0
Fibric Acids	244	0	0
Fluoroquinolones	138	0	1
Forteo	100	13	0
Growth Hormones	153	20	2
H2 Antagonists	5	0	0
Hematinics	6	0	0
Heparin and Related Products	12	0	0
HMG CoA Reductase Inhibitors	226	0	1
Inhaled Glucocorticoids	36	0	0
Inspra	9	0	0
Ketolides	106	0	0
Leukocyte Stimulants	13	0	0
Leukotriene Receptor Antagonists	899	2	1
Long Acting Beta Agonists	28	0	0
Loop Diuretics	29	1	0

Page 1 of 2

Table 3.8 -- continued --



Indiana Medicaid - Preferred Drug List Prior Authorizations

From 10/01/2004 To 03/31/2005	Client ID:	INCAID	
	Run Date:	7/11/2005	

F10111 10/01/2004 10 03/31/2003			
Therapeutic Class or Preferred Drug Description	Α	D	S
Macrolides	103	1	0
Miotics - OIPR	240	1	1
Narcotics	636	5	2
Nasal Steroids and Antihistamines	617	1	1
Non-Sedating Antihistamines	3,790	11	6
Ophthalmic Antibiotics	121	0	0
Opthalmic Mast Gell Stabilizers	16	0	0
Other Lipotropics	122	0	0
Otic Antibiotics	97	1	0
Plan Limits	3,921	10	12
Platelet Aggregation Inhibitors	136	0	0
Proton Pump Inhibitors	13,416	25	30
SERMS - Bone Resorption Agents	569	1	1
Short Acting Beta Agonists	676	0	0
Skeletal Muscle Relaxants	616	1	2
Smoking Deterrent Agents	5	0	0
Stadol NS	2	0	0
Systemic Vitamin A Derivatives	3	0	0
Thiazolidenediones	757	4	1
Topical Estrogen Agents	61	0	0
Topical Vitamin A Derivatives	110	0	0
TPL Claim Too Old	336	2	1
TPL Within Filing Limit	54	1	0
Triptans	131	0	0
Urinary Tract Antispasmodics- Antiincontinence	261	0	1
Vaginal Antimicrobials	566	0	0
Sum:	40,432	513	107

Page 2 of 2

CHAPTER 4 PHARMACY BENEFIT EXPENDITURE CHANGES ASSOCIATED WITH THE PREFERRED DRUG LIST PROGRAM

Introduction

This Chapter explores the economic impact of the Preferred Drug List (PDL) program on the pharmacy benefit component of the Indiana State Medicaid Program. The analysis is based on claims paid August 2002 through September 2003.

The "Methods" section describes how pharmacy reimbursement data is integrated with CMS rebate data to estimate the net cost savings for individual PDL classes, taking into account background variability such as price changes, rebate amount changes and seasonal variation in medication use.

The section on "Factors Affecting PDL Program Savings" highlights the effect of CMS federal rebates, preferred drug selection, shifting market share, and utilization on the net cost savings. The dynamic nature of these factors may impact the various therapeutic classes on the Preferred Drug List in different ways. Therefore, in the section on "Performance of Individual Therapeutic Classes Subject to Preferred Drug List," the performance outcomes and some of the factors that affect the outcomes are summarized.

The "Results" section of this chapter reports the overall preferred drug market share changes, estimated expenditure changes, estimated rebate receipt changes, and estimated net savings experienced by the State. It is important to understand that one consequence of shifting utilization to lower priced medications is a potential reduction in CMS rebates. The CMS rebate reduction can be greater than the expenditure savings for a given therapeutic class.

Since clinical considerations are the primary basis for preferred drug selection, scenarios existed where there are no cost savings associated with choosing a particular drug within a therapeutic class. Drug costs are defined as the price paid to the pharmacy less rebates paid to the State by drug manufacturers. The rebates presently received by Indiana Medicaid are those mandated by the federal government through Centers for Medicare and Medicaid Services (CMS) regulations. Changes in rebate amounts arising from market share shifts to other medications within a class affected net savings to the State.

Extraction of CMS Rebate Data

Rebate data is available in the ACS Data Warehouse. The CMS data provides a unit rebate amount (URA) for each national drug code (NDC)²², the applicable quarter of service, a termination date if needed, and a load date indicating when the record was loaded into the warehouse. Data loads occur quarterly and often include new records updating the URA for earlier quarters of service.

In order to provide a reasonable basis for estimating the ultimate rebate effect of a PDL, the unit rebate amounts were "fixed" when necessary. The basic file consisted of the latest URA available for each quarter of service that was greater than zero. If there were no values greater than zero for an NDC/quarter of service combination²³, then a value greater than zero for that NDC was borrowed from the nearest adjacent quarter, searching forward and backward. If that method failed to populate the URA cell, then the minimum URA that was greater than zero for that NDC's drug name and quarter of service across all NDCs was used, if one existed. If the value was still zero, then no further effort was made to fix the missing URA value for that NDC/quarter of service combination.

Preferred Drug List Savings Calculations

The method used for estimating PDL savings was based on market share changes for all medications in a therapeutic class covered by the PDL. Market share changes directly affects PDL savings by anticipating *what would have been* spent if no PDL had been implemented *versus what was spent* by having the PDL in place. The method estimated savings for each therapeutic class impacted by the PDL; beginning with the month the therapeutic class was added to the PDL. For each class, month of service, and NDC in the class, the amount paid per claim, the rebate per claim, the net expenditure per claim²⁴, and the NDC's market share²⁵ of total claims were calculated for all the drugs in that class. Multiplying each NDC's market share times its average amount (e.g., paid per claim) and then adding those products for all NDCs in the class was how the overall average per claim amounts for each class were calculated. Those average amounts were the "observed" or "actual" average amount paid per claim, average rebate amount per claim and average net expense per claim.

^{2 -}

²² NDC refers to the National Drug Code number that uniquely identifies all commercially marketed drug products by their name, strength, package size, delivery route and manufacturer/distributor.
²³ Just over 5 percent of the NDC/month-of-service combinations required for the Indiana study were

²³ Just over 5 percent of the NDC/month-of-service combinations required for the Indiana study were missing URA values. The missing URAs involved about 4 percent of the claims. The above described search process found appropriate URA values for 90 percent of the claims with missing URAs.

²⁴ Net expenditure per claim was the amount paid per claim less the rebate amount per claim.

²⁵ An NDC's market share was the NDC's percentage share of all claims for the medications in the therapeutic class on the PDL in a given month. If, for example, in a month of service, there were 2,500 claims for an NDC and there were 12,000 claims for all the preferred and nonpreferred medications in the NDC's therapeutic class, then the NDC's market share for that month would be 20.6 percent.

Factors Affecting PDL Program Savings

CMS Rebates

CMS rebates have a significant impact on the financial performance of a PDL program. The "Methods" section of this chapter discusses the extraction and use of CMS unit rebate data to estimate potential rebate receipts for all medications in each affected therapeutic class and the "fixes" performed to the CMS data to infer values when they are either missing for a quarter or were clearly erroneous. The volume of claims involved in the "fixes" is small (see "Methods" discussion). These "fixes" enabled us to make reasonable predictions of the amount billed for drugs in a therapeutic class over time. These fixes are conservative, but still may result in modest underestimation of rebate amounts for some therapeutic classes.

Supplemental Rebates

Many Medicaid programs solicited rebates directly from participating manufacturers to supplement the CMS rebates for their preferred drugs. Supplemental rebates enhance the CMS rebates and contribute to additional reductions in the net cost of preferred drugs. These rebates are more stable and could limit the variability associated with the fluctuations of the CMS rebates. However, at the time of this evaluation supplemental rebates had not yet been implemented in the Indiana Medicaid PDL and therefore have no impact on the reported results.

Preferred Product Selection

Preferred drug selections are based on initial comparisons of clinical efficacy and safety, followed by a comparison of the relative economic benefits of the medications in each therapeutic class. Due to superior clinical efficacy, there are times when the selected "preferred" drugs were more costly (had higher prices or significantly lower rebates) than the nonpreferred drugs in the class so that switching to preferred drugs actually increased the State's net cost. The most costly example of this phenomenon was the August 2002 implementation of the nonsedating or minimally-sedating antihistamines where prices increased and rebates were significantly lower than expected. Another example was the Februrary 2003 implementation of the Bone Resorption Suppression Agents.

As noted in the "Results" section, the preferred drug selection process created some PDL classes containing either all preferred drugs, no preferred drugs, or a mix of preferred drugs representing a very high share of the total number of claims in the class. In those situations, there are generally few opportunities to secure positive savings through the shifting of claims volumes to less costly drugs.

Price Changes and Other Cost Factors

As indicated above, a Preferred Drug List program is expected to derive savings by shifting prescribing and utilization habits to preferred drugs. Accordingly, the method used to evaluate savings should capture the effects of market changes while controlling

12/20/2005 Page 56 of 69

for other determinants of cost and cost change. Price and rebate changes affect the ACS savings estimates only when they changed the relative net expense of drugs that were being switched from nonpreferred to preferred in a given month. If there were shifts to or from drugs having a month-to-month change in their net cost relative to other drugs in a class, ACS' method would capture the net cost savings/increases associated with movement to the less expensive or more costly drugs. If the drug mix in a therapeutic class remained stable, then changes in ingredient prices, unit rebate amounts or copayments would not alter the calculated net savings (see "Methods" section).

Inflation, a cause of price change, is an important determinant of pharmacy expenditure growth. The cost-savings methodology used in this report takes into account inflation by estimating net savings based on the average net cost of drugs in a month of service. This methodology does not estimate savings based on any month-to-month change in average expenditure or average rebate which might be due to price inflation or rebate changes generated by manufacturers.

Results

12/20/2005

Overall, the PDL program significantly increases the utilization of preferred drugs relative to their nonpreferred alternatives. In January 2002, 7-months prior to PDL implementation and education about the PDL program, **75.2%** of the claims were for preferred drugs. By July 2002, the month preceding implementation of the first therapeutic classes on PDL, the preferred claim-share had already increased to 79%. By September 2003, the preferred claim-share had increased to almost **95.8%** (See Table 4.1). In September 2004, the preferred claim share had shifted slightly downward **to 93.8%** and rises six months later to **98.7%** in March 2005.

The change in market share shift toward preferred drugs yielded financial benefits for the State of Indiana in both its first and second year of operation.

Year 1. Based on the analysis of the PDL program for 52 classes between August 2002 and August 2003, ACS estimates the total annualized²⁶ net savings after CMS federal rebate reductions to be approximately **\$8.9 million** (see Tables 4.2 and 4.3). The net pharmacy benefit savings represented 4.4% of total net expenditures projected had the PDL program not been instituted.

<u>Year 2</u>. Based on the follow-up analysis of the PDL program for 54 classes between October 2003 to September 2004, ACS estimates the net total annualized²⁷ net savings after CMS rebate reductions to be approximately **\$1.12 million** (see Table 4.4 and 4.5).

Page 57 of 69

²⁶ Because different classes had been operational for periods ranging from less than 1 month to just over 13 months at the close of the period studied, the observed results were annualized assuming 12 months of operation for all classes. The expected annual payments/rebates/net expenditures were the values that would have been expected had there been no savings/rebate changes over a 1-year period (e.g., observed payments plus the estimated payment savings for the period)

payments plus the estimated payment savings for the period). ²⁷ For Report #2 or Year 2 analysis, because different classes had been operational for different periods of time, with quantity limits and other on-going changes during the period studied, the observed results were

TABLE 4.1. Percent Preferred Before and After PDL Implementation – Year 1

				Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Pre- ferred Change from Year 1 to Year 2	
Original Imple- menta- tion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates	(negative means lost preferred market share from Year 1)	
Aug-02	Oct03, Jun04	Z2A	Z2A - Non-Sedating Antihistamines	24.3%	93.7%	(766,838.25)	94.1%	\$2,263,851	\$12,792,012	0.4%	
Sep-02	Oct03, Jul04 Sep03,	A4D	A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	\$63,051	\$4,487,225	-1.0%	
OOP OL	Apr04, Jul04	D4K	D4K - Proton Pump Inhibitors	34.9%	82.4%	6,214,934.91	73.7%	(\$567,862)	\$27,441,018	-8.8%	
		J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)	99.8%				
	Mar-04		J7A - ALPHA/BETA Adrenergic Blockers				100.0%	(\$4,493)	\$1,946,456		
	Oct-03		J7C - BETA Adrenergic Blockers				99.9%	(\$25,723)	\$4,251,595		
Oct-02		APA	J7B - ALPHA Adrenergic Blockers A9A - Calcium Channel Blockers	94.0%	97.6%	(00.470.40)	99.5%	\$1,777	\$196,361 \$10,546,741	6.3% 0.5%	
		R1M	A9A - Calcium Channel Blockers R1M - Loop Diuretics	94.0%	97.6%	(86,178.42) 6,799.96	98.2%	(\$29,766) (\$4,197)	\$2,092,918	0.5%	
		M9P	M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160 561 02)	98.4%	(\$13,781)	\$12,192,138	-1.7%	
	Oct-03	C4N	C4N - Thiazolidenediones	52.5%	90.1%	713,168.64	98.7%	(\$121,660)	\$10,005,660	8.7%	
	Jul-04	A4D	A4D - ACE Inhibitor VV/Diuretics	21.8%	90.0%	(2,602.00)	87.8%	\$1,778	\$474,777	-2.3%	
	Oct-03	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	95.0%	35,170.70	93.1%	\$8,798	\$1,713,257	-1.9%	
	Oct-03	A4K	A4K - Ace Inhibitor w/CCB	95.2%	99.0%	(32,358.44)	100.0%	\$1,984	\$1,379,662	1.0%	
	Oct03,Mar04 May04	M4E	M4E - Statins	99.0%	99.6%	(340.978.41)	100.0%	(\$25,315)	\$27,053,472	0.4%	
Dec-02	Apr-04	H3F	H3F - Triptans	56.1%	93.4%	200,335.05	92.2%	(\$10,884)	\$2,310,830	-1.2%	
	Oct03, Jul04	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	(\$691)	\$1,808,520	-0.1%	
	Oct03, Apr04	J5D	JSD - Beta Agonists	85.4%	96.0%	1,204,858.72	95.2%	\$296,897	\$9,828,446	-0.8%	
		P5A	P5A - Inhaled Glucocorticoids	77.5%	97.7%	100,611.16	93.1%	\$3,897	\$6,609,036	-4.6%	
	Apr-04	Q7E/P	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	(\$3,718)	\$4,410,943	-2.5%	
		Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	\$476,326	\$32,682,425	0.1%	
	Mar-04	A4F	A4F - Angiotensin Receptor Blockers	45.7%	88.5%	5,100.34	85.8%	(\$1,146)	\$1,983,049	-2.7%	
		WIWXY	W1W/X/Y - Cephalosporins	71.7%	99.4%	450,721.61	91.0%	(8770)	61 101 104	-8.4%	
	May-04	AAIAAVI	W1W - Cephalosporins W1X - 2nd Gen Cephalosporins				99.8%	(\$776) \$21,949	\$1,121,164 \$605,519		
Jan-03			VVI Y - 3rd Gen Cephalosporins				76.3%	(\$39,268)	\$2,818,778	-8.3%	
	_	WID	VVID - Macrolides	99.7%	100.0%	(45,111.79)	96.7%	(\$31,765)	\$4,704,570	-3.3%	
	Oct03, Sep04	WIQ	W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	(\$213,557)	\$6,388,476	-2.1%	
	Apr-04	W3B	VA3B - Antifungals	87.4%	94.7%	408,366.70	92.5%	(\$1,910,968)	\$2,530,547	-2.2%	
	Oct03, Jul04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	(\$68,242)	\$3,404,555	-0.6%	
Feb-03		M9K	M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	\$1,520,082	\$3,346,150	10.7%	
	Jul-04 Oct03, Jul04	P4L C4KLM	P4L - SERM's/Bone Resorption Suppression Agents C4K/L/M - Antidiabetic Agents	62.5% 99.1%	95.6% 99.9%	(166,722.99)	93.4%	(\$12,038) (\$102,582)	\$7,837,621 \$7,096,763	-2.2% -1.1%	
		D7L	D7L - Bile Acid Sequestrants	50.6%	71.2%	25,373.09	72.2%	\$14,737	\$250,538	1.0%	
	Apr-04	H3A	H3A - Brand Name Narcotics	89.3%	98.1%	279.897.57	98.4%	(\$330.671)	\$36,088,507	0.3%	
May-03		н6н	H6H - Skeletal Muscle Relaxants	54.6%	95.6%	381,280.18	93.7%	(\$73,697)	\$4,176,686	-1.9%	
		M4E	M4E - Fibric Acids	90.9%	95.4%	(98,801.99)	95.2%	\$43,340	\$2,306,332	-0.2%	
	Mar-04	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	(\$44,670)	\$6,166,399	-0.6%	
	-	J3A	J3A - Smoking Cessation	69.8%	85.1%	28,877.34	84.8%	(\$9,744)	\$798,560	-0.4%	
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	(1,330.08)					
		L9B L1B/5H/9B	L9B - Topical Vitamin A Derivatives L1B/L5H/L9B - Acne Agents (Age 25 and under)	97.9%	99.3%	(13,515.48)	88.8%	\$19,305	\$705,976		
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (over 25)				0.0%	(\$75,700)	\$699,809	-1.7%	
	Jul-04	L5F, L1A	LSF - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	(\$7,869)	\$483,398	37.7%	
	5UI-04	N1B	N1B - Hematinics	100.0%	93.8%	(164,984,36)	100.0%	\$42,735	\$7,654,848	6.2%	
Jul-03	-	N1C	N1C - Leukocyte Stimulants	80.0%	95.7%	175,583.46	83.9%	(\$18,367)	\$1,252,066	-11.8%	
	-	P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	\$0	0.0%	\$0	\$631,913	0.0%	
	Mar04, Apr04,										
	Jul04	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5% 70.4%	(82,448.16) (11.003.97)	79.6%	(\$6,787)	\$2,565,907	4.1% 5.6%	
	Jul-04	Q6I Q6R	Q6I - Eye Antibiotic/Corticosteroid Combos Q6R - Eye Antihistamines	14.4% 99.8%	100.0%	17,824.12	76.0% 98.9%	(\$3,958) (\$3,696)	\$91,520 \$300,017	-1.1%	
	Oct-03	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	(6.623.87)	42.4%	(\$366)	\$128.023	1.7%	
	Oct03, May04	Q6W	Q6W - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	(\$101,146)	\$682,031	14.5%	
	May-04	Q8W/	Q8FAV - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	\$33,215	\$942,401	1.3%	
		D4F	D4F- Anti-ulcer/H.Pylori Agents			11,185.20	0.0%	\$3,859	\$21,614	0.0%	
		Q4F	Q4F - Vaginal Antimicrobials	8.7%	59.3%	76,684.93	67.1%	(\$403)	\$58,480	7.8%	
Aug-03	Apr-04	Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	(7,353.26)	82.0%	(\$2,350)	\$215,240	-18.0% -9.1%	
Aug-03	May-04	Q5F	Q5F - Topical Antifungal Agents	64.0%	92.6%	49,135.59	83.6%	\$18,217	\$2,150,110	-9.1%	
	Oct-03 Apr-04	W5A W5A	W5A - Anti-Herpetic Agents W5A - Influenza Agents	41.7% 0.0%	51.6%	247,807.66					
	whi-na	W5AM6A	WSA - Intiuenza Agents WSA - Anti-Herpetic & Influenza Agents	0.076	0.076	0.00	96.0%	(\$33,673)	\$1,621,203	44.4%	
Sep-03	Jul-04	S2B	S2B - Cox II's	0.0%	0.0%		0.0%	\$199,691	\$11,892,289	0.0%	
May-04	May-04	R1H	R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone	N/A	N/A		100.0%	(\$5,031)	\$656,763		
	L'	52	TOTAL ALL PDL PROGRAMS	75.2%		\$8,909,550	93.8%	\$1,128,929	\$298,601,311	1.1%	
Total				75 20	05.9%	. NY 4014 5511	91.8%	K1 129 020	- CZUR 601 311		

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

annualized assuming the second 12 months of operation (actual dates were: Oct03-Sep04) for all classes. Estimates were derived from prescription claims data obtained from OMPP.

TABLE 4.2. Year 1 Estimated Annualized Savings Analysis – Detailed Report by PDL Class

					SHO	VVING PA	MENT AND REB	ATE.	AMOUNTS							
		Total Estimated				elves			pected Total Cla	ame '	Twelve Month:			Savin	mated Ann gs/Change	es As
		Mo	onths of	Full Operatio	n				Been In	Ope	ration			Percent	of Expect	ed Tota
Implemen-	7		B. t. et			xpense	Expected	Exq		Ехр	ected Annual		ected Annual	Payment	Rebate	Net
	Therapeutic Class Z2A - Non-Sedating Antihistamines	Payment Savings \$ 796,552		e Changes (1,563,391)		/ings (766,838)	Annual Claims 228,199	\$	Payments 13,808,062	s	Rebates 4,542,696	S	et Expenses 9,265,366	Savings 5.8%	Changes -34.4%	-8.
	A4D - ACE Inhibitor	\$ 239,540		(187,996)		51,544	276,378	\$	7,933,106	S	1,712,045	S	6,221,061	3.0%		-0.
	D4K - Proton Pump Inhibitors	\$ 6,543,025		(328,090)		214,935	265,472	-		s	9,041,588	s	25,832,980	18.8%	-3.6%	24.
***10/9/2002	A9A - Calcium Channel Blockers	\$ 2,814	\$	(88,992)	\$	(86,178)	219,408	\$	10,235,570	S	1,496,807	\$	8,738,762	0.0%	-5.9%	-1.
10/9/2002	J7A/B/C - ALPHA/BETA Adrenergic Blockers	\$ (95,311)	\$	33,670	\$	(61,641)	267,232	\$	5,597,942	\$	922,035	\$	4,675,907	-1.7%	3.7%	-1
	M9P - Platelet Aggrtegation Inhibitors	\$ (247,175)		86,614		(160,561)	84,572		ap capea	\$	2,442,227	\$	6,263,170	-2.8%	3.5%	-2
	R1M - Loop Diuretics	\$ 27,028		(20,228)		6,800	268,499	\$	- Incention	\$	109,164	\$	2,493,006	1.0%		0
	A4D - ACE Inhibitor W/Diuretics	\$ (300)		(2,302)		(2,602)	24,536	\$	786,088		147,663	\$	638,425	0.0%	-1.6%	-0
	A4F - Angiotensin Receptor Blockers w/Diuretics	\$ 44,731 \$ (19.337)		(9,560)		35,171	30,835		1,674,204		575,378	\$	1,098,827	2.7%	-1.7% -3.3%	-3
	A4K - Ace Inhibitor w/CCB C4N - Thiazolidenediones	\$ (19,337) \$ (1,359,761)		(13,022) 2,072,930		(32,358) 713,169	20,204 83,128	\$	1,239,990 10,288,250		394,042 2,917,608	S	845,948 7,370,642	-13.2%		-3
	H3F - Triptans	\$ 283,488		(83,153)		200.335	20,647	-		S	922,647	S	2,195,841	9.1%	-9.0%	9
	J5D - Beta Agonists	\$ 1,868,973		(664,114)		,204,859	336,226	\$	13,093,264	•	3,541,474	S	9.551.790	14.3%		12
	M4E - Statins	\$ (216,561)		(124,418)		(340,978)	263,731	5		s	7,022,609	\$	16,928,637	-0.9%	-1.8%	-2
	PSA - Inhaled Glucocorticoids	\$ 238,929		(138,318)		100,611	60,964		6,260,304		1,874,529	\$	4,385,775	3.8%		2
	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Ster			26,116		(5,285)	81 538			\$	2,232,028	\$	2,564,680	-0.7%	1.2%	-0
	Q9B - Benign Prostatic Hypertrophy Agents	\$ (4,157)		(390)	5	(4,547)	26,713		1,675,861	\$	541,518		1,134,343	-0.2%	-0.1%	-0
***12/10/2002	Z4B - Leukotriene Receptor Antagonists	\$ (18,630)	\$	(1,943)	\$	(20,573)	92,629	\$	7,266,881	\$	1,774,259	\$	5,492,622	-0.3%	-0.1%	-0
	A4F - Angiotensin Receptor Blockers	\$ (170,665)		175,766		5,100	40,028	\$		\$		\$	1,199,610	-9.9%		0
	W1D - Macrolides	\$ (42,428)		(2,684)		(45,112)	140,688	\$		8	1,150,613		4,623,522	-0.7%		-1
	W1Q - Fluoroquinolones	\$ 80,312	-	(46,835)		33,477	87,305	\$		\$	2,224,411	\$	3,740,225	1.3%		0
	W1W/X/Y - Cephalosporins	\$ 901,394	-	(450,672)		450,722	148,068	\$		\$	1,117,118		4,057,009	17.4%		11
	W3B - Antifungals	\$ 720,430		(312,064)		408,367	34,720	\$		\$	792,432	\$	2,035,398	25.5%		
	H6J - Antiemetic/Antivertigo Agents	\$ 91,931		(21,608)		70,323	6,006	\$		\$	1,066,644	\$	1,394,942	3.7%		40
	M9K - Heparin and Related Products P4L - SERM's/Bone Resorption Suppression Agent	\$ (379,076) \$ (54.168)		62,130 (112.555)	. ,	(316,946) (166,723)	17,420 113,018	\$	2,868,251 7.280.960	S	376,183 1.712.836	\$	2,492,068 5.568.124	-13.2% -0.7%		-12
	C4K - Antidiabetic Agents	\$ (54,168) \$ (16.131)		(1,971)	. ,	(18,102)	150,749	\$		S	1,712,036	S	3,500,124	-0.7%		-0
	D7L - Bile Acid Sequestrants	\$ 55,319		(29,946)		25.373	5,458	\$		S	78,074	\$	304.281	14.5%		-0
	H3A - Brand Name Narcotics	\$ 665,416		(385,518)		279,898	950,794	\$		\$	9,029,868	\$	28,315,823	1.8%		1
	H6H - Skeletal Muscle Relaxants	\$ 937,899		(556,619)		381,280	171,950	\$	6,916,328	s	1,137,393	\$	5,778,935	13.6%		6
	M4E - Fibric Acids	\$ (98,679)		(123)		(98,802)	51,744	\$	2,596,024	s	686,445	\$	1,909,579	-3.8%		-5
5/14/2003	R1A - Urinary Tract Antispasmodic/Anti Incontineni	\$ 681,181	\$	(94,578)	\$	586,603	99,451	\$	7,449,965	\$	1,591,629	\$	5,858,336	9.1%	-5.9%	10
7/21/2003	J3A - Smoking Cessation	\$ 37,541	\$	(8,664)	\$	28,877	8,164	\$	725,455	\$	71,390	\$	654,065	5.2%	-12.1%	4
*7/21/2003	L1B - Systemic Vitamin A Derivatives	\$ 4,252	\$	(5,583)	\$	(1,330)	92	\$	39,917	\$	38,188	\$	1,729	10.7%	-14.6%	-76
	LSF - Antipsoriatics	\$ 20,751	\$	(10,923)		9,827	3,452	\$	410,779	\$	144,066	\$	266,714	5.1%		3
	L9B - topical Vitamin A Derivitives	\$ 17,702		(31,217)		(13,515)	4,348	\$	272,090	\$	95,665	\$	176,425	6.5%		-7
	N1B - Hematinics	\$ (267,654)		102,670		(164,984)	9,412			\$	1,310,599	\$	4,411,949	-4.7%		-3
	N1C - Leukocyte Stimulants	\$ 202,904		(27,321)		175,583	764	\$	1,161,282	\$	249,624	\$	911,658	17.5%		19
	P4B - Bone Formation Stimulating Agents	\$ -	\$	-	\$		364	\$	184,198	\$	25,659	\$	158,540	0.0%	0.0%	0
	Q6G - Miotics/Other intraocular Pressure Reducers Q6I - Eye Antibiotic/Corticosteroid Combos	\$ (2,057) \$ 73,469		(80,391) (84,473)		(82,448) (11,004)	51,348 4,320	\$	2,566,857 232,597	S	610,539 166,199	\$	1,956,318 66,398	-0.1% 31.6%		-4 -16
	Q6R - Eye Antihistamines	\$ 19,948		(2,124)		17,824	6,808		441,779	S	163,026	5	278,753	4.5%		-10
	Q6U - Ophthalmic Mast Cell Stabilizers	\$ 36,673		(43,296)		(6,624)	2,416		149,268	s	66,687	s	82,580	24.6%		-8
	Q6W - Ophthalmic Antibiotics	\$ 151,168		(169,667)		(18,499)	33,372				395,957	\$	461,686	17.6%		-4
	Q8FAV - Otic Antibiotics	\$ (10,342)		(32,593)		(42,936)	29,248		1,102,343		316,976	\$	785,367	-0.9%		-5
	D4F - Antiulcer/H.Pylori Agents	\$ 11,621		(436)		11,185	882		224,258		87,773		136,485	5.2%	-0.5%	8
8/6/2003	Q4F - Vaginal Antimicrobials	\$ 168,470	\$	(91,785)	\$	76,685	10,086	\$	409,533	8	163,081	\$	246,452	41.1%	-56.3%	31
*8/6/2003	Q4K - Topical Estrogen Agents	\$ (347)	\$	(7,006)	\$	(7,353)	6,402	\$	364,305	\$	178,704	\$	185,601	-0.1%	-3.9%	-4
	Q5F - Topical Antifungal Agents	\$ 334,832		(285,697)		49,136	77,142		2,976,506	\$	621,985	\$	2,354,520	11.2%		2
	W5A - Anti-Herpetic Agents	\$ 210,266	\$	37,542	\$	247,808	19,572	\$	1,638,384	\$	598,318	\$	1,040,067	12.8%	6.3%	23
	W5A - Influenza Agents															
9/17/2003	S3B - NSAIDS/COX II DL PROGRAMS	\$ 12,434,379		(3,524,829)	ė o	,909,550	4,936,501		270,872,141		70,104,418		200,767,723	4.59%	-5.03%	4.4
	ses With Only Limited Limited Potential For Market	v 12,454,313	ą.	(0,024,029)	v 0,	,000,000	4,000,001	Φ	210,012,141	Ŷ	10,104,410	*	200,101,123	4,0376	-0.0378	40
hare Changes		\$ (136,883)	\$	(571,946)	\$ ((708,829)	2,360,481	\$	115,967,894	\$	29,425,857	\$	86,542,036	-0.12%	-1.94%	-0.8
otals for All C	lasses With Substantial Potential For Change	\$ 12,571,262	\$	(2,952,883)	\$ 9,	,618,379	2,576,019	\$	154,904,247	8	40,678,561	\$	114,225,687	8.12%	-7.26%	8.4
	ses With Adverse Savings Potential	\$ 636,446	\$	(1,980,304)	\$ (1,	,343,858)	589,193	\$	37,436,796	\$	11,017,627	\$	26,419,169	1.70%	-17.97%	-5.0
	ses With Both Potential For Substantial Change and al For Positive Savings	\$ 11,934,816	\$	(972,579)	\$ 10,	,962,237	1,986,827	\$	117,467,451	\$	29,660,934	\$	87,806,517	10.16%	-3.28%	123
	Classes With Limited Potential for Cha	nge:														
		ingo. * Classes with non	on-prefe	erred drugs												
		Classes with no p	referred	drugs												
					41	- OF										
		Classes with prefi														

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

12/20/2005 Page 59 of 69

TABLE 4.3. Year 1 Estimated Annualized Savings Analysis Summary

Indiana Medicaid

Annualized Estimated Savings Analysis Summary - Year 1

Year 1 - Count of Therapeutic Classes		Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)
Classes		o	0/ B/	(Adjusted Annualized Net Savings minus
	Category of Therapeutic Classes	% Pre-ferred		, , , , , , , , , , , , , , , , , , , ,
52	TOTAL ALL PDL PROGRAMS	75.2%	95.8%	\$8,909,550
	Totals for Classes With Only Limited Potential For			
21	Market Share Changes (>95%)			(\$708,829)
6	Classes With all Preferred Drugs (100%)			
	Totals for Classes with Substantial Potential For			
22	Change (<=94%)			\$9,618,379

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

TABLE 4.4. Year 2 Estimated Annualized Savings Analysis Summary

Indiana Medicaid

Annualized Estimated Savings Analysis Summary - Year 2

Year 2 - Count of Therapeutic Classes		Sept/Oct 04 (End Year 2 of PDL Program)	Annualized Net	Annualized Estimated Amount Paid Total
			(Adjusted Annualized Net	Rebates. Contains both
			Savings minus	state and
		% Preferred	Fed. Rebate)	Federal
54	TOTAL ALL PDL PROGRAMS	93.8%	\$1,128,929	\$298,601,311
	Totals for Classes With Only Limited Potential			
22	For Market Share Changes (>95%)		\$1,036,467	\$195,966,447
6	Classes With all Preferred Drugs (100%)		\$478,337	\$71,857,023
	Totals for Classes with Substantial Potential For			
21	Change (<=94%)		(\$199,404)	\$298,601,311
5	Classes with all NonPreferred Drugs (0%)		\$127,850	\$13,245,624

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

TABLE 4.5. Year 2 Estimated Annualized Savings Analysis – Detailed Report by PDL Class

				Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Pre- ferred Change from Year 1 to Year 2
Original Imple- menta- tion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates	(negative means lost preferred market share from Year 1)
Aug-02	Oct03, Jun04	Z2A	Z2A - Non-Sedating Antihistamines	24.3%	93.7%	(766,838.25)	94.1%	\$2,263,851	\$12,792,012	0.4%
	Oct03, Jul04	A4D	A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	\$63,051	\$4,487,225	-1.0%
Sep-02	Sep03,	D4K			82.4%			(\$567.862)	#07 444 040	-8.8%
	Apr04, Jul04	J7ABC	D4K - Proton Pump Inhibitors	34.9% 94.2%	93.5%	6,214,934.91 (61,640,62)	73.7%	(\$567,862)	\$27,441,018	-8.8%
	Mar-04	JABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers J7A - ALPHA/BETA Adrenergic Blockers	34.276	93.5%	(61,640.62)	100.0%	(\$4,493)	\$1,946,456	
	Oct-03		J7C - BETA Adrenergic Blockers				99.9%	(\$25,723)	\$4,251,595	
Oct-02			J7B - ALPHA Adrenergic Blockers				99.5%	\$1,777	\$196,361	6.3%
		A9A	A9A - Calcium Channel Blockers	94.0%	97.6%	(86,178.42)	98.2%	(\$29,766)	\$10,546,741	0.5%
		R1M	R1M - Loop Diuretics	93.1%	99.0%	6,799.96	99.8%	(\$4,197)	\$2,092,918	0.8%
		M9P	MSP - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	(\$13,781)	\$12,192,138	-1.7%
	Oct-03	C4N	C4N - Thiazolidenediones	52.5%	90.1%	713,168.64	98.7%	(\$121,660)	\$10,005,660	8.7%
	Jul-04 Oct-03	A4D A4F	A4D - ACE Inhibitor VWDiuretics A4F - Angiotensin Receptor Blockers w/Diuretics	21.8%	90.0%	(2,602.00)	87.8% 93.1%	\$1,778 \$8,798	\$474,777 \$1,713,257	-2.3% -1.9%
	Oct-03	A4K	A4F - Angiotensin Receptor Blockers wildurences A4K - Ace Inhibitor w/CCB	95.2%	99.0%	35,170.70 (32,358.44)	100.0%	\$1,984	\$1,379,662	1.0%
	Oct03,Mar04					, , , ,				
Dec-02	May04	M4E	M4E - Statins	99.0%	99.6%	(340,978.41)	100.0%	(\$25,315)	\$27,053,472	0.4%
	Apr-04	H3F	H3F - Triptans	56.1%	93.4%	200,335.05	92.2%	(\$10,884)	\$2,310,830	-1.2%
	Oct03, Jul04	Q9B JSD	G9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86) 1,204,858.72	98.8% 95.2%	(\$691) \$296.897	\$1,808,520 \$9,828,446	-0.1% -0.8%
	Oct03, Apr04	P5A	JSD - Beta Agonists PSA - Inhaled Glucocorticoids	77.5%	97.7%	1,204,656.72	93.1%	\$296,697	\$6,609,036	-4.6%
	Apr-04	Q7E/P	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	(\$3,718)	\$4,410,943	-2.5%
	-	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	\$476,326	\$32,682,425	0.1%
	Mar-04	A4F	A4F - Angiotensin Receptor Blockers	45.7%	88.5%	5,100.34	85.8%	(\$1,146)	\$1,983,049	-2.7%
			WIW/X/Y - Cephalosporins	71.7%	99.4%	450,721.61				
	May-04	WIWKY	VV1VV - Cephalosporins				99.8%	(\$776)	\$1,121,164	
Jan-03	l '		W1X - 2nd Gen Cephalosporins				96.9%	\$21,949	\$605,519	0.00/
		WID	W1Y - 3rd Gen Cephalosporins W1D - Macrolides	99.7%	100.0%	(45 444 70)	76.3% 96.7%	(\$39,268) (\$31,765)	\$2,818,778 \$4,704,570	-8.3% -3.3%
	Oct03, Sep04	WIQ	W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	(\$213.557)	\$6,388,476	-2.1%
	Apr-04	W3B	W3B - Antifungals	87.4%	94.7%	408,366.70	92.5%	(\$1,910,968)	\$2,530,547	-2.2%
	Oct03, Jul04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	(\$68,242)	\$3,404,555	-0.6%
Feb-03	-	M9K	MSK - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	\$1,520,082	\$3,346,150	10.7%
	Jul-04	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	(166,722.99)	93.4%	(\$12,038)	\$7,837,621	-2.2%
	Oct03, Jul04	C4KLM	C4K/LM - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	(\$102,582)	\$7,096,763	-1.1%
	 Apr-04	D7L H3A	D7L - Bile Acid Sequestrants H3A - Brand Name Narcotics	50.6% 89.3%	71.2% 98.1%	25,373.09 279,897.57	72.2% 98.4%	\$14,737 (\$330,671)	\$250,538 \$36,088,507	1.0% 0.3%
May-03	Apr-04	H6H	H6H - Skeletal Muscle Relaxants	54.6%	95.6%	381,280.18	93.7%	(\$73,697)	\$4,176,686	-1.9%
		M4E	M4E - Fibric Acids	90.9%	95.4%	(98,801.99)	95.2%	\$43,340	\$2,306,332	-0.2%
	Mar-04	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	(\$44,670)	\$6,166,399	-0.6%
	-	J3A	J3A - Smoking Cessation	69.8%	85.1%	28,877.34	84.8%	(\$9,744)	\$798,560	-0.4%
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	(1,330.08)				
		L9B	L9B - Topical Vitamin A Derivatives	97.9%	99.3%	(13,515.48)			4705.070	
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under)				88.8%	\$19,305	\$705,976	4 70/
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (over 25)				0.0%	(\$75,700)	\$699,809	-1.7%
	Jul-04	LSF, L1A N1B	LSF - Antipsoriatics N1B - Hematinics	55.1% 100.0%	62.3% 93.8%	9,827.40 (164.984.36)	100.0%	(\$7,869) \$42,735	\$483,398 \$7,654,848	37.7% 6.2%
Jul-03		N1C	N1C - Leukocyte Stimulants	80.0%	95.7%	175,583.46	83.9%	(\$18,367)	\$1,252,066	-11.8%
00F-03		P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	\$0	0.0%	\$0	\$631,913	0.0%
	Mar04, Apr04,									
	Jul04	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	(82,448.16)	79.6%	(\$6,787)	\$2,565,907	4.1%
		Q6I Q6R	Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	70.4%	(11,003.97)	76.0%	(\$3,958)	\$91,520 \$200.017	5.6% -1.1%
	Jul-04 Oct-03	QBU	Q6R - Eye Antihistamines Q6U - Ophthalmic Mast Cell Stabilizers	99.8%	100.0% 40.7%	17,824.12 (6,623.87)	98.9% 42.4%	(\$3,696) (\$366)	\$300,017 \$128,023	1.7%
	Oct03, May04	Q6VV	Q6/V - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	(\$101,146)	\$682,031	14.5%
	May-04	Q8VV	Q8FAV - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	\$33,215	\$942,401	1.3%
		D4F	D4F- Anti-ulcer/H.Pylori Agents			11,185.20	0.0%	\$3,859	\$21,614	0.0%
		Q4F	Q4F - Vaginal Antimicrobials	8.7%	59.3%	76,684.93	67.1%	(\$403)	\$58,480	7.8%
A 000	Apr-04	Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	(7,353.26)	82.0%	(\$2,350)	\$215,240	-18.0%
Aug-03	May-04	Q5F	QSF - Topical Antifungal Agents	64.0%	92.6%	49,135.59	83.6%	\$18,217	\$2,150,110	-9.1%
	Oct-03 Apr-04	VV5A VV5A	WSA - Anti-Herpetic Agents WSA - Influenza Agents	0.0%	0.0%	247,807.66 0.00				
		WSAM6A	WSA - Influenza Agents WSA - Anti-Herpetic & Influenza Agents	0.0%	0.0%	0.00	96.0%	(\$33,673)	\$1,621,203	44.4%
Sep-03	Jul-04	S2B	S2B - Cox II's	0.0%	0.0%		0.0%	\$199,691	\$11,892,289	0.0%
May-04	May-04	R1H	R1H - Inspra (Step Edit: Requires prev.tx w/spironalactone	N/A	N/A		100.0%	(\$5,031)	\$656,763	
		52				\$8,909,550	93.8%	£4 430 000		4.40
Total		52	TOTAL ALL PDL PROGRAMS Totals for Classes With Only Limited Potential	75.2%	95.8%	\$0,505,330	53.0%	\$1,128,929	\$298,601,311	1.1%
			For Market Share Changes (>95%) Totals for Classes with Substantial Potential For			(\$708,829)		\$1,159,285	\$209,868,834	
	100		Change (<94%)		L	\$9,618,379		\$1,128,929	\$298,601,311	

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

1st Half Year 3. Based on the analysis of the PDL program for 62 classes between October 1, 2004 and March 31, 2005, ACS estimates the **total 6-month** ²⁸ **net savings after CMS federal rebate reductions to be approximately \$1.8 million** (see Table 4.4).

 TABLE 4.6. 1st Half Year 3 Estimated Annualized Savings Analysis Summary

Indiana Medicaid

Annualized Estimated Savings Analysis Summary - Year 2.5 Adjusted Sept/Oct 04 **Annualized Net Annualized** (End Year Savings Over 26-Estimated 2.5 of PDL 31 Months Post-**Amount Paid** Year 2.5 -Program) PDL (2.5 Yr of Total (Year 2.5) Count of PDL) **Category of Therapeutic Classes** Therapeutic Classes (Adjusted Prior to Rebates **Annualized Net** Contains both Savings minus state and % Preferred Fed. Rebate) Federal portion. 62 TOTAL ALL PDL PROGRAMS 98.7% \$1,860,986 \$144,999,032 Totals for Classes With Only Limited Potential For Market Share Changes (=>95%) \$87,558,525 10 Classes With all Preferred Drugs (100%) \$41,234,215

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Totals for Classes with Substantial Potential For

Classes with all NonPreferred Drugs (0%)

Change (<=94% or < 95%)

19

The grand total net pharmacy benefit savings representing total net expenditures projected had the PDL program not been instituted less federal rebate changes and minus cost to administer the program is estimated to be approximately **\$8.15** to **\$10.02** million from August 2002 to March 2005.

An additional estimated **\$ 6.81 million** in savings began to be realized from October 1, 2004 to March 31, 2005 in supplemental rebates.

Formatted

\$57,440,508

12/20/2005 Page 62 of 69

 $^{^{28}}$ For Report #3 or 1^{st} half of Year 3 analysis, because different classes had been operational for different periods of time, and because new quantity limits and other on-going changes occurring during the period studied, the observed results are estimated 6-month figures according to months 26-31 of operation (Actual dates were: Oct 1, 2004-Mar 31, 2005) for all classes. Estimates were derived from prescription claims data obtained from OMPP.

Results by Therapeutic Class

The ACS Market Share Change Methodology generated data that enabled analysis of the relative performance of individual therapeutic classes within the preferred drug list (see Tables 4.2 and 4.5 and 4.7).

This section summarizes the market share changes and annualized financial performance of each therapeutic class, and offers comments to explain some of the dynamics that affected performance.

The summaries are grouped according to several scenarios of observed payment and net savings or by three programmatic features that constrained opportunities for change. In the discussion below, the classes are categorized primarily by the circumstances that existed at the time the preferred drug list was implemented.

Generally, the preferred drug market share had stabilized by the end of Year 2 of the PDL program and there were no large market shifts from 6-months after implementation of each class (end of Year 1) through to the end of Year 2, except in those classes that were newly implemented. Some classes changed slightly over time. The majority of classes that *did* show market share changes reverted back slightly toward non-preferred agents. This indicates the need for on-going education. Variations in overall savings performance that occurred during Year 2 were largely due to changes in unit rebate amounts or pricing changes for one or more medications in the class, and a few newly implemented classes.

Sometimes more expensive PDL drugs were chosen for clinical reasons, based on anticipation of better outcomes. Additionally, some increase in expenditures occurred due to unanticipated rebate or product price changes occurring after the selection of preferred drugs.

Some performance changes were related to quantity or age limits that were being rolled out throughout month 13-31 post-implementation. Changes due to quantity or age limits will need additional evaluation to determine their success upon either decreasing inappropriate utilization or effecting net savings after federal rebates. Additional evaluation is needed because limits had not been instituted long enough for an evaluation period and were not a part of this study. This section of the study involved evaluation of market share changes and associated net savings.

In general, savings from implementing a PDL program can occur several ways:

- Savings from starting new users on preferred agents
- Savings from switching users from non-preferred to preferred agents
- Reoccurring savings based on a previous change (residuals)
- Offsetting revenue increases from rebates
- Reduction of unneeded prescriptions

TABLE 4.7. 1st half Year 3 Estimated Savings & Market Share – by PDL Class

		_	Indiana Medicaid PDL Program Evalu							
		Percen	t Preferred Before & After PDL In	nplemer	itation					
				Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Sept/Oct 04 (End Year 2 of PDL Program)	Mar 05 (End Year 2.5 of PDL Program)	6-month Amount Paid Total (Year 2 to 2.5)	Adjusted 6- month Net Savings Over 26-31 Months Post- PDL (2 to 2.5 Yr of PDL)	
Original Imple- menta- tion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Pre-ferred	% Preferred	% Pre- ferred	Prior to Rebates	Net Savings minus Fed.& Supp. Rebate)	
non Date	Change Date	mer class	THE ENNED BROOS	Terred	70 PTO-TOTTOU	70 FT GT GT GT	lelled	Kenates	Kepatej	
Aug-02	Oct03, Jun04	Z2A	Z2A - Non-Sedating Antihistamines (RX)	24.3%	93.7%	94.1%	95.0% 100.0%	\$2,964,955 \$879,547	\$117,245	
Aug-02	Oct03, Jun04 Oct03, Jul04	Z2A A4D	Z2A - Non-Sedating Antihistamines (OTC) A4D - ACE Inhibitor	33.1%	98.5%	97.5%	99.0%	\$2,047,479	\$263,053	
Sep-02	Sep03, Apr04, Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (RX)	34.9%	82.4%	73.7%	82.9%	\$12,479,925	\$2,921	
	Sep03, Apr04, Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (OTC)				100.0%	\$302,514	(\$156,019)	
	04,0004	J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	99.8%				
	Mar03, Mar05		J7A - ALPHA/BETA Adrenergic Blockers			100.0%	100.0%	\$1,220,547	\$28,159	
Oct-02	Oct-03		J7C - BETA Adrenergic Blockers J7B - ALPHA Adrenergic Blockers			99.9%	99.7%	\$2,393,184 \$93,226	\$41,622 \$9,299	
	Oct-02	A9A	A9A - Calcium Channel Blockers	94.0%	97.6%	98.2%	97.7%	\$5,292,286	\$145,418	
	Oct-02 Oct-02, Dec-04	R1M M9P	R1M - Loop Diuretics	93.1%	99.0%	99.8% 98.4%	99.9% 89.9%	\$1,008,530 \$6,371,035	\$54,246 (\$4,216)	
	Oct-03, Dec-04	C4N	M9P - Platelet Aggregation Inhibitors C4N - Thiazolidenediones	52.5%	90.1%	98.7%	100.0%	\$4,804,426	\$60,985	
	Jul-84, Oct-84	A4D	A4D - ACE Inhibitor W/Diuretics	21.8%	90.0%	87.8%	99.8%	\$226,028	\$24,745	
	Oct-03 Oct-03	A4F A4K	A4F - Angiotensin Receptor Blockers vv/Diuretics	50.7%	95.0% 99.0%	93.1%	91.9% 100.0%	\$943,226 \$816,181	\$19,974 (\$9.876)	
	Oct03,Mar04,		A4K - Ace Inhibitor w/CCB	95.2%					(7-1)	
	May04, Oct04	M4E	M4E - Statins	99.0%	99.6%	100.0%	100.0% 96.7%	\$14,116,066 \$1,254,559	(\$11,947)	
Dec-02	Apr-04, Oct-04 Oct03, Jul04	H3F Q9B	H3F - Triptans Q9B - Benign Prostatic Hypertrophy Agents	56.1% 100.0%	93.4% 98.9%	92.2%	96.7%	\$1,254,559 \$960,890	\$37,731 \$9,441	
	Oct03, Apr04,								l	
	Oct04, Jan05 Oct-04	J5D P5A	J5D - Beta Agonists P5A - Inhaled Glucocorticoids	85.4% 77.5%	96.0% 97.7%	95.2% 93.1%	99.2% 98.7%	\$2,635,363 \$3,776,578	\$181,265 (\$11,706)	
	Apr84, Oct84	Q7E/P	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	97.5%	93.9%	\$3,776,578 \$2,319,622	(\$11,706) (\$17,300)	
	Oct-04	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	100.0%	100.0%	\$3,595,288	\$53,845	
	Dec-02, Mar-04 Mar-04	J5G A4F	J5G - Beta agonists and corticosteroids A4F - Angiotensin Receptor Blockers	45.7%	88.5%	85.8%	100.0% 81.1%	\$4,064,822.00 \$1,144,388	(\$59,871) \$25,258	
	May-04	WIWXY	W1VV/X/Y - Cephalosporins	71.7%	99.4%	91.0%		\$1,144,300	\$25,250	
		WIW	VV1VV - Cephalosporins			99.8%	99.8%	\$533,783	\$55,867	
Jan-03		WIX	W1X - 2nd Gen Cephalosporins W1Y - 3rd Gen Cephalosporins			96.9% 76.3%	96.0% 99.5%	\$259,646 \$2,499,552	\$30,686 (\$316,232)	
		WID	VV1D - Macrolides	99.7%	100.0%	96.7%	98.0%	\$3,888,379	(\$363,283)	
	Oct03, Oct04	WIQ	W1Q - Fluoroquinolones	100.0%	100.0%	97.9% 92.5%	100.0%	\$3,663,389	\$52,952	
	Apr-04 Oct03, Jul04,	W3B	V/3B - Antifungels	87.4%	94.7%	52.5%	94.6%	\$1,143,603	\$26,476	
Feb-03	Dec04	M9K	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	98.4%	91.8% 99.5%	\$1,929,797 \$1,872,178	\$44,818 \$28,350	
	Jul-04	P4L	M9K - Heparin and Related Products P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	93.4%	91.4%	\$3,996,045	\$405,039	
	Oct03, Jul04,			00.40	00.00	00.00	98.9%	\$3,341,050	#202 420	
	Dec04	C4KLM D7L	C4K/L/M - Antidiabetic Agents D7L - Bile Acid Sequestrants	99.1% 50.6%	99.9% 71.2%	98.8% 72.2%	76.9%	\$134,541	\$263,420 \$2,960	
May-03	Apr-84, Dec-84	нза	H3A - Brand Name Narcotics	89.3%	98.1%	98.4%	92.4%	\$18,478,467	\$953,972	
	Jun-05 Oct-04	H6H M4E	H6H - Skeletal Muscle Relaxants M4E - Fibric Acids	54.6% 90.9%	95.6% 95.4%	93.7% 95.2%	93.3% 98.7%	\$2,010,910 \$1,316,251	\$153,037 (\$162,419)	
	Mar-04, Dec-04,									
	Jun-05 Dec-04, Jun-05	R1A J3A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent J3A - Smoking Cessation	75.7% 69.8%	98.3% 85.1%	97.7% 84.8%	97.9% 99.9%	\$3,182,170 \$473,179	\$61,984 (\$27,178)	
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	04.0%	99.976	\$473,179	(827,170)	
	·	L9B	L9B - Topical Vitamin A Derivatives	97.9%	99.3%					
	Oct-03, Jul-04	L1B/5H/9B L1B/5H/9B	L1B&SH&9B - Acne Agents (Age 25 and under) L1B&SH&9B - Acne Agents (over 25)			88.8%	86.0% 0.0%	\$294,603 \$53,740	\$7,414 \$3,600	
	Oct-03, Jul-04 Jul-04	LSF, L1A	LSF - Antipsoriatics	55.1%	62.3%	100.0%	98.6%	\$269,710	(\$1,161)	
		N1B	N1B - Hematinics	100.0%	93.8%	100.0%	100.0%	\$3,969,610	(\$337,505)	
Jul-03		N1C P4B	N1C - Leukocyte Stimulants P4B - Bone Formation Stimulating Agents	80.0%	95.7% 0.0%	83.9%	0.0%	\$457,166 \$394,684	\$26,348 (\$12,152)	
	Mar04, Apr04,			64.7%	75.5%	79.6%	81.3%	\$1,269,112		
	Jul04, Jun05	Q6G Q6I	Q6G - Miotics/Other intraocular Pressure Reducers Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	75.5%	79.6%	77.0%	\$1,269,112	\$37,549 (\$1)	
	Jul-04, Dec-04	Q6R	Q6R - Eye Antihistamines	99.8%	100.0%	98.9%	98.8%	\$144,137	(\$1) (\$6,156)	
	Oct-03 Oct03, May04,	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	42.4%	93.5%	\$45,323	\$5,673	
	Oct04	Q6VV	Q6VV - Ophthalmic Antibiotics	94.3%	83.7%	98.2%	98.0%	\$352,374	\$5,217	
	May-84, Oct-84	G8W	Q8FAV - Otic Antibiotics	97.6%	97.9%	99.2%	92.4%	\$439,466	(\$15,949)	
		D4F	D4F- Anti-ulcer/H.Pylori Agents			0.0%	0.0%	\$48,521	\$3,472	
	Apr. 04	Q4F Q4K	Q4F - Vaginal Antimicrobials Q4K - Topical Estrogen Agents	8.7% 100.0%	59.3% 100.0%	67.1% 82.0%	84.0% 86.8%	\$37,947 \$106,218	(\$7,784) \$1,812	
Aug-03	Apr-04 May-04	Q4K Q5F	QSF - Topical Estrogen Agents QSF - Topical Antifungal Agents	100.0% 64.0%	92.6%	82.0%	97.3%	\$865,417	\$134,759	
. ag-uu	Oct-03, Oct-04	VV5A	WSA - Anti-Herpetic Agents	41.7%	51.6%	96.0%	97.1%			
	Apr-04 Apr-04, Dec-04,	W5A	WSA - Influenza Agents	0.0%	0.0%	0.0%				
	Mar-05	W5A/H6A	WSA - Anti-Herpetic & Influenza Agents			96.0%	99.9%	\$1,116,184	(\$42,841)	
Sep-03	Dec-04, Jun-05 Dec-04, Jun-05	D4K-H2A Rx D4K-H2A OTC	D4K-H2RA H-2 Antagonists - Rx D4K-H2RA H-2 Antagonists - OTC				95.2% 100.0%	\$2,270,438 \$35,860	\$27,811 \$0	
	Jul-04	S2B	S2B - Cox II's	0.0%	0.0%	0.0%	0.0%	\$3,268,015	\$539,171	
May-04	May-04; Oct-04	M4E Other	M4E Other Lipotropic Agents			400 ***	100.0%	\$1,286,822	(\$447,410)	
	May-04 Oct-04	R1H A1D	R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone) A1D - Agents to treat COPD	N/A	N/A	100.0%	98.2% 95.4%	\$331,868 \$3,348,099	\$15,880 \$168,373	
Oct-04	Oct-2005, Mar- 05	M4I	M4I - CCB w/HMGs				100.0%	\$85,958	(\$21,481)	
	Oct-04	W9A	W9A - Ketolides				0.0%	\$29,693	\$9,120	
			TOTAL ALL PDL PROGRAMS	75.2%	95.8%	93.8%	98.7%	\$144,999,032		
		52	Total PDL Classes Studied			54	62	Total PDL Clas	ses Studied	
		21	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%)			22	28	\$ 87,558,525	\$1,860,986	
			Totals for Classes with Substantial Potential For							
		22 6	Change (<=94%) Classes With all Preferred Drugs (100%)			21 6	19 10	\$ 57,440,508 \$ 41,234,215		
		4	Classes with all Preferred Drugs (100%) Classes with all NonPreferred Drugs (0%)			5	5	\$ 3,794,653		
						54	62	Total for All PDL		

12/20/2005 Page 64 of 69 ACS Government Healthcare Solutions © 2005 All rights reserved. Information was deemed proprietary and confidential.

Table 4.7 also shows the preferred drug market share changes by PDL class. In summary, the scenarios used in the analysis with the number of classes covered were:

- 1. Classes with Positive Net Savings (PDL program noted savings even if CMS rebates were reduced)
- 2. Classes with Negative Net Savings (PDL program noted cost increases due to shifts in market share)
- 3. Classes with Zero Savings (PDL program noted break even with prior years)
- 4. Classes Where Preferred Drug Share Exceeded 95% of all Claims in Class at Program Start (22 classes in Year 1; 21 classes in Year 2).
- 5. Classes with All Preferred Drugs (6 classes in Year 1; 6 classes in Year 2).
- 6. Classes with No Preferred Drugs, Only Nonpreferred (3 classes in Year 1; 4 classes in Year 5).

The savings produced by the first scenario was the most desirable to a State Medicaid program because the State's savings were up-front in the form of payment reductions. Up-front payment reductions would be more desirable than paying out more for medications and then waiting several months for the benefit in the form of increased rebate payments. The last three scenarios would appear to offer limited opportunity for savings or losses due to market share shifting from implementing a PDL program. As described below, there were changes among individual drugs in those classes that had an impact on net savings.

1-3. Classes with Positive Net Savings, Negative Net Savings and Zero Changes.

Count of Classes		Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Amount Paid
36	Classes with Negative Net Savings (Costs more)	-\$3,906,560	\$197,930,422
17	Classes with Positive Net Savings	\$5,035,489	\$100,038,975
1	Classes with Zero Net Savings (Break Even)	\$0	\$631,913

4. <u>Classes Where Preferred Drugs Had Over 95% of Market Share At Program Start</u>

Year 1 of PDL Program

A9A – CCBs (Calcium Channel Blockers)

R1M – Loop Diuretics

M4E -- Statins

Z4B – Leukotriene Receptor Antagonists

W1D – Macrolide Antibiotics

M9K – Heparin

C4K – Anti-Diabetic Drugs

H3A – Brand name Narcotics

L9B – Topical Vitamin A Derivatives

Q6R – Eye Antihistamines

Q6F/W - Otic Antibiotics

12/20/2005 Page 65 of 69

Year 2 of PDL Program

Therapeutic Class	PDL by 7	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	04 (End	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Preferred Change Yr1 to Yr2
A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	\$63,051	\$4,487,225	-1.0%
J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)				
J7C - BETA Adrenergic Blockers				99.9%	(\$25,723)	\$4,251,595	
J7B - ALPHA Adrenergic Blockers				99.5%	\$1,777	\$196,361	6.3%
A9A - Calcium Channel Blockers	94.0%	97.6%	(86,178.42)	98.2%	(\$29,766)	\$10,546,741	0.5%
R1M - Loop Diuretics	93.1%	99.0%	6,799.96	99.8%	(\$4,197)	\$2,092,918	0.8%
M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	(\$13,781)	\$12,192,138	-1.7%
C4N - Thiazolidinediones	52.5%	90.1%	713,168.64	98.7%	(\$121,660)	\$10,005,660	8.7%
Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	(\$691)	\$1,808,520	-0.1%
Q7E/P - Nasal Anti-histamine/Anti- inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	(\$3,718)	\$4,410,943	-2.5%
W1W - Cephalosporins				99.8%	(\$776)	\$1,121,164	
W1X - 2nd Gen Cephalosporins				96.9%	\$21,949	\$605,519	
W1D - Macrolides	99.7%	100.0%	(45,111.79)	96.7%	(\$31,765)	\$4,704,570	-3.3%
W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	(\$213,557)	\$6,388,476	-2.1%
H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	(\$68,242)	\$3,404,555	-0.6%
M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	\$1,520,082	\$3,346,150	10.7%
C4K/L/M - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	(\$102,582)	\$7,096,763	-1.1%
H3A - Brand Name Narcotics	89.3%	98.1%	279,897.57	98.4%	(\$330,671)	\$36,088,507	0.3%
M4E - Fibric Acids	90.9%	95.4%	(98,801.99)	95.2%	\$43,340	\$2,306,332	-0.2%
R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	(\$44,670)	\$6,166,399	-0.6%
Q6R - Eye Antihistamines	99.8%	100.0%	17,824.12	98.9%	(\$3,696)	\$300,017	-1.1%
Q6W - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	(\$101,146)	\$682,031	14.5%
Q8F/W - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	\$33,215	\$942,401	1.3%
W5A - Anti-Herpetic & Influenza Agents				96.0%	(\$33,673)	\$1,621,203	44.4%

5. Classes with All Preferred Drugs

Classes with all preferred drugs at the beginning of PDL program implementation (in other words there were no non-preferred drugs in the class) have no opportunity for savings from patients being switched from non-preferred to preferred agents.

Year 1 of PDL Program

Q7P/P7E – Nasal Anti-Inflammatory Steroids (100% Preferred Year 1 to 97.5% Year 2)

Q9B – Benign Prostatic Hypertrophy Agents (100% Preferred Year 1 to 98.8% Year 2)

W1Q – Fluoroquinolones (100% Preferred Year 1 to 97.9% Year 2)

L1B – Systemic Vitamin A Derivatives (100% Preferred Year 1 to 88.8% Year 2)

N1B – Hematinics (100% Preferred Year 1 and stayed 100.0% in Year 2)

Q4K – Topical Estrogen Agents (100% Preferred Year 1 to 82.0% Year 2)

12/20/2005 Page 66 of 69

Year 2 of PDL Program

Therapeutic Class	Jan-02 (Before PDL by 7 months)	of PDL	Net Savings Over 1st 12 Months	04 (End	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Preferred Change Yr1 to Yr2
A4K - Ace Inhibitor w/CCB	95.2%	99.0%	(32,358.44)	100.0%	\$1,984	\$1,379,662	1.0%
M4E - Statins	99.0%	99.6%	(340,978.41)	100.0%	(\$25,315)	\$27,053,472	0.4%
Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	\$476,326	\$32,682,425	0.1%
L5F - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	(\$7,869)	\$483,398	37.7%
N1B - Hematinics	100.0%	93.8%	(164,984.36)	100.0%	\$42,735	\$7,654,848	6.2%
R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone)	N/A	N/A		100.0%	(\$5,031)	\$656,763	

Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	
\$ 478,337	\$71,857,023

6. Classes with No Preferred Drugs

<u>Year 1 of PDL Program</u> P4B – Bone Formation Stimulating Drugs

D4F – Antiulcer/H. Pylori Drugs

Year 2 of PDL Program

Therapeutic Class	Jan-02 (Before PDL by 7 months)	of PDL	Net Savings Over 1st 12 Months	04 (End Year 2 of PDL	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Preferred Change Yr1 to Yr2
L1B/L5H/L9B - Acne Agents (over 25)				0.0%	(\$75,700)	\$699,809	-1.7%
P4B - Bone Formation Stimulating Agents	0.0%	0.0%	\$0	0.0%	\$0	\$631,913	0.0%
D4F- Anti-ulcer/H.Pylori Agents	0.0%	0.0%	11,185.20	0.0%	\$3,859	\$21,614	0.0%
S2B - Cox II's				0.0%	\$199,691	\$11,892,289	0.0%

Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total
\$127,850	\$13,245,624

Page 67 of 69

Conclusions on PDL Program Savings

The Indiana Medicaid Preferred Drug List Program as implemented through March 31, 2005 involved 62 therapeutic classes. In year one, the program succeeded in increasing the share of preferred drugs relative to their nonpreferred alternatives from 75.2% in January 2002 to 95.8% by September 2003. In year two, the program succeeded in retaining market share at 93.8% preferred drugs dispensed, and increased by the 1st half of year 3 to 98.7% preferred drugs dispensed.

The pharmacy net savings resulting from implementing a PDL program were estimated to be between \$7.40 to 8.16 million in Year 1, and an additional \$380,000 to (-\$370,000) in Year 2, and an additional \$1.11 to 1.49 million over 6-months from Year 2 to 1st half of Year 3. This figure does not include additional estimated savings of \$6.81 million from supplemental rebates added beginning in October 2004.

Over the 2 ½ year period after implementation of the PDL program, the overall net pharmacy savings are estimated to be between \$8.15 million to \$10.02 million plus approximately \$6.81 million in supplemental rebates for an estimated total savings since implementation of approximately \$15–16.8 million.

The program included many therapeutic classes with very limited opportunities for shifting from nonpreferred to preferred medications. Some of these classes experienced cost increases rather than cost savings because of changes among the preferred medications. The program also included several classes where the net costs for the preferred medications were greater than the net costs of the nonpreferred drugs. In those classes, the preferred drugs were considered clinically superior and safer than the lower cost drugs in the class. Shifting a prescription from nonpreferred to preferred in those classes increased the net cost.

Given the ability of the PDL program to increase preferred drug market share, the choice of therapeutic classes with opportunities for such shifts and the selection of the most cost-effective drugs as preferred were crucial to fully realizing the potential financial benefits of the preferred drug list. The selected drugs must be clinically appropriate to the needs of the target population and the expected net cost (expected payment amount per claim less expected rebate amount per claim) of preferred drugs must be lower than that of the nonpreferred drugs that they are likely to be replacing. It is necessary to consider both the price paid to pharmacies and the federal rebates received from manufacturers in assessing relative net costs. If the average net cost for preferred drugs in a class is more costly than the nonpreferred drugs, then shifting to preferred drugs increases rather than decreases costs.

To produce substantial savings with a preferred drug list, it is also important to limit the number of drugs deemed as "preferred." Overly inclusive lists limit savings since they reduce the number of nonpreferred drug prescriptions eligible for change. In addition, the excluded AAAX drugs should be considered as part of the PDL since their percentage of the overall cost will continue to climb.

12/20/2005 Page 68 of 69

Limitations of the Savings Estimation Methodology

There is nothing inherent in the design of a preferred drug program that causes overall utilization increases. The program does not promote the new use of particular drugs (i.e., a PDL is not intended to encourage the use of a drug that has not been previously in use) rather an intervention occurs when a prescription for a nonpreferred drug is being processed. At this point in time, the nonpreferred medication may be dispensed, the prescription may be changed to a preferred medication, or the therapy may be terminated. Thus, there is the intrinsic possibility of some utilization decline in association with a PDL intervention. If there is any decrease in utilization, the calculated savings will decline accordingly. If the reduction in utilization is due to reduction of inappropriate utilization by the PDL intervention, then there are real utilization savings for the State in the form of fewer overall claims. This methodology does not adjust the PDL savings estimates to capture such program savings. It is very difficult to discern the extent to which any observed reduction in utilization in a PDL class was due to the intervention or to other factors. Therefore, the estimates presented may underestimate the program savings. Additionally, if prescribing practitioners switch their patients to the preferred drug, or start prescribing the preferred drug before the implementation of each PDL phase, the methodology does not capture the potential savings.